

# Resin-based Dental Restorative Material

## CE ESTELITE UNIVERSAL FLOW REF PE01

### ENGLISH

Carefully read all information, precautions, notes and materials before using ESTELITE UNIVERSAL FLOW.

#### ■ PRODUCT DESCRIPTION AND GENERAL INFORMATION

1) ESTELITE UNIVERSAL FLOW is a low viscosity, light-cured, radiopac composite resin for use in indirect and direct restorations. Direct placement of ESTELITE UNIVERSAL FLOW into a prepared cavity allows for easy handling.

2) ESTELITE UNIVERSAL FLOW incorporates Radical-Amplified Photopolymerization initiator technology (RAP technology). RAP technology facilitates a shortened curing time and ample working time. See the table below for curing time and increment depth.

#### ■ INDICATIONS FOR FILLING AND CURING

3) ESTELITE UNIVERSAL FLOW comes in three viscosities, High, Medium and Super Low. Each type contains spherical silica-zirconia filler and composite filler as indicated in below table. The composite filler offers reduced polymerization shrinkage stress due to its round shape. The spherical filler contained in ESTELITE UNIVERSAL FLOW (mean particle size: 200 nm, particle size range: 100 to 300 nm) facilitates excellent gloss retention and wear resistance.

#### ■ SHADE

Available shade in each type is as below:

Type	Filler Loading
High	69% by weight (55% by volume)
Medium	71% by weight (57% by volume)
Super Low	70% by weight (56% by volume)

4) ESTELITE UNIVERSAL FLOW contains Bisphenol A diglycidyl propoxypolymerized dimethacrylate (Bis-GMA), Bisphenol A polyhydroxy methacrylate (Bis-MPEPP), Triethylene glycol dimethacrylate (TEGMA), 1,6-bis(methyl-ethyl)-hexylbenzylaminotrimethyl hexane (UDMA), Mequinol, Dimethyl hydroxyl tolene and UV absorber.

5) ESTELITE UNIVERSAL FLOW is available in either SYRINGE (L-SYRINGE or SYRINGE (Medium only)) or Pre Loaded Tip (PLT (Medium only)).

#### ■ PRECAUTIONS

ESTELITE UNIVERSAL FLOW contains methacrylic monomers and UV absorber. DO NOT use ESTELITE UNIVERSAL FLOW for patients allergic to or hypersensitive to methacrylic and related monomers, to UV absorber or to any of the other ingredients.

#### ■ PRECAUTIONS

1) DO NOT use ESTELITE UNIVERSAL FLOW for any patient other than those listed in these instructions. ESTELITE UNIVERSAL FLOW only as directed herein.

2) ESTELITE UNIVERSAL FLOW is designed for sale and use by dental clinical professionals only. It is not designed for sale by non-dental clinical professionals.

3) DO NOT use ESTELITE UNIVERSAL FLOW if the safety seals are broken or appear to have been tampered with.

4) IF ESTELITE UNIVERSAL FLOW causes an allergic reaction or hypersensitivity, discontinue its use immediately.

5) Use examination gloves (elastic, vinyl or latex) if it will come in contact with ESTELITE UNIVERSAL FLOW to avoid the possibility of allergic reactions from methacrylic monomers or UV absorber. Note: Certain substances/materials may penetrate through examination gloves.

If ESTELITE UNIVERSAL FLOW comes in contact with the eyes, remove and dispose of the gloves, and wash hands thoroughly with water as soon as possible.

6) Avoid contact of ESTELITE UNIVERSAL FLOW with eyes, mucosal membrane, skin and clothing.

If ESTELITE UNIVERSAL FLOW comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.

If ESTELITE UNIVERSAL FLOW comes in contact with the mucosal membrane, wipe the affected area with water as soon as possible after the restoration is completed.

If ESTELITE UNIVERSAL FLOW comes in contact with the skin or clothing, immediately saturate the area with an alcohol soaked cotton swab or gauze.

Instruct the patient to rinse his mouth immediately after treatment.

7) ESTELITE UNIVERSAL FLOW should not be ingested or aspirated. Ingestion or aspiration may cause serious injury.

8) To avoid the unintentional ingestion of ESTELITE UNIVERSAL FLOW, do not leave it unsupervised within the reach of patients and children.

9) Clean the placement site with water, soapsuds or gogles should be worn at all times.

10) When using bonding-unit protective eye shields, glasses or goggles should be worn at all times.

11) This product is designed to be used at room temperature (18 ~ 30°C / 62 ~ 84°F). Allow product to reach room temperature prior to use. Cold material may be difficult to extrude.

#### ■ INDICATIONS FOR FILLING AND CURING

ESTELITE UNIVERSAL FLOW is designed to be used by either a halogen, LED, or Plasma Arc light with curing time between 0 ~ 500 ms. Be sure to light-cure ESTELITE UNIVERSAL FLOW extra-ordinarily and check the time needed for complete hardening of ESTELITE UNIVERSAL FLOW with your light-curing unit before performing the bonding procedure. The following table summarizes the relationship between curing time and increment depth.

Relationship between curing time and increment depth:

Light type	Intensity (mW/cm <sup>2</sup> )	Curing time (seconds)	Increment depth (mm) <sup>1)</sup>			
			CE, BW, A1, A2, A3, A5, A4, B3	A5	OPOA2 OPRA3 OPRA4	OPOA2 OPRA3 OPRA4
Halogen	600	10	1.8	1.6	1.3	
		20	2.3	2.0	1.6	
	800	10	2.0	1.7	1.5	
		20	2.4	2.1	1.7	
LED	1200	5	1.8	1.6	1.3	
		10	2.2	2.0	1.6	
	2300	3	1.7	1.5	1.2	
		10	2.0	1.8	1.5	
Plasma Arc	1200	3	1.7	1.5	1.2	

1) Increment depth was determined on the basis of test results performed in accordance with "depth of cure" of ISO 4049

#### ■ SPECIAL NOTES FOR THE USE OF PLT

1) PLTs are designed for single patient use only. Do not re-cap and/or re-use the PLT tip once material has been dispensed for that patient.

2) Dispensers are not provided for ESTELITE UNIVERSAL FLOW. Use a dispenser that fits the PLT of ESTELITE UNIVERSAL FLOW. For proper use and proper dispensing, see manufacturer's instruction.

3) Use light, controlled pressure to prevent any continued extrusion of material following pressure release.

#### ■ STORAGE

1) Store ESTELITE UNIVERSAL FLOW at temperatures between 0 ~ 25°C (32 ~ 77°F).

2) Avoid direct exposure to light and heat.

3) DO NOT use ESTELITE UNIVERSAL FLOW after the indicated date of expiration of the syringe or PLT package.

#### ■ DISPOSAL

To safely dispose of excess ESTELITE UNIVERSAL FLOW, extrude unused portion from SYRINGE or PLT and light-cure before disposal.

#### ■ CLINICAL PROCEDURE

##### 1. Cleaning

Thoroughly clean the tooth surface with a rubber cup and a fluoride-free paste then rinse with water.

##### 2. Shade Selection

Prior to selection of tooth, select the appropriate shade of ESTELITE UNIVERSAL FLOW using shade guide provided for ESTELITE UNIVERSAL FLOW.

##### 3. Isolation

A rubber dam is the preferred method of isolation.

##### 4. Cavity Preparation

Prepare the cavity. In case where no cavity preparation has been made (caries-free cervical defects), clean the tooth surface with a rubber cup and a fluoride-free cleaning paste. Rinse thoroughly with water.

##### 5. Bonding System

Calciun hydroxide should be applied if the cavity is in close proximity to the pulp. DO NOT USE EUGENOL-BASED MATERIALS to protect the pulp as these materials will inhibit curing ESTELITE UNIVERSAL FLOW. ESTELITE UNIVERSAL FLOW is not indicated for direct pulp capping.

##### 6. Bonding System

Apply a bonding system according to its manufacturer's instructions.

- In case of porcelain/composite repairs be sure to condition the surface porcelain/composite with a sealant coupling agent BEFORE performing the bonding procedure.

##### 7- PLT (Medium)

Please read ■ SPECIAL NOTES FOR THE USE OF PLT before use.

- Load the PLT into a dispenser that fits the PLT.

##### 7-1. SYRINGE (High, Medium and Super Low)

Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-2. L-SYRINGE (High, Medium and Super Low)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-3. SYRINGE (Medium)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-4. SYRINGE (High, Medium and Super Low)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-5. SYRINGE (Medium)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-6. SYRINGE (High)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-7. SYRINGE (Super Low)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-8. SYRINGE (Plastic Tip)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-9. SYRINGE (Medium)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-10. SYRINGE (High)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-11. SYRINGE (Super Low)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-12. SYRINGE (Plastic Tip)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-13. SYRINGE (Medium)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-14. SYRINGE (High)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-15. SYRINGE (Super Low)

- Hold the nozzle and turn the cap counter-clockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (plastic tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]

##### 7-16. SYRINGE (Plastic Tip)

- Hold

