

6257182201 ASTE IA **ENGLISH** **БЪЛГАРСКИ** **FRANÇAIS** **ΕΛΛΗΝΙΚΑ**
ITALIANO **PORTUGUES** **ROMANA** **ESPAÑOL** **TURKÇE**

Resin-based Dental Restorative Material



ESTELITE ASTERIA SYRINGE

ESTELITE ASTERIA PLT

Last updated 2022-02-28 Rev.E

ENGLISH

Read all information, precautions and notes before using.

PRODUCT DESCRIPTION AND GENERAL INFORMATION

- ESTELITE ASTERIA is a light-cured, radiopaque composite resin for use in anterior and posterior restorations indicated for all various lesion classes, including minimal or no-preparation type restorations. ESTELITE ASTERIA contains 82% by weight (71% by volume) silica-zirconia filler and composite filler. A high filler load offers decreased polymerization shrinkage. Every umonomer filler contained in ESTELITE ASTERIA is a spherical filler (mean particle size: 200 nm, particle size range: 100 to 300 nm) that enables excellent gross retention and wear resistance. ESTELITE ASTERIA contains Bisphenol A di(2-hydroxy propoxy) dimethacrylate (Bis-GMA), Bisphenol A poly(ethylene methacrylate) (Bis-PEMP), 1,6-bis(methacryloxyethyl)hexane dimethylol urethane (UDMA), triethylene glycol dimethacrylate (TEGDMA), Mequimol, Dibutyl hydroxyl toluene, and UV absorber.
- ESTELITE ASTERIA incorporates Radical-Amplified Photopolymerization initiator technology (RAP technology). RAP technology facilitates a shortened light curing time and ample working time (90 sec.). Please see the table depicting the relationship between curing time and increment depth (INDICATIONS FOR FILLING AND CURING).
- ESTELITE ASTERIA is provided either in SYRINGE or Pre-Loaded PLT (PLT).

SHADE

ESTELITE ASTERIA contains 7 Body shades and 5 Enamel shades. The ESTELITE ASTERIA shading system is designed to mimic a wide shade range of natural dentition by layering the appropriate shades selected from 2 categories: Body and Enamel.

Component	Shade	Tip
Body	A1B, A2B, A3B, A3.5B, A4B, B3B, B4, Natural Enamel (NE)	Body shades are designed for reconstructing the dentin layer. The Body shades should cover all enamel margins.
	Trans Enamel (TE)	TE is recommended for the proximal wall. WE is suggested as an alternative to NE in whiter cases.
	White Enamel (WE)	WE is recommended for the proximal wall. WE is suggested as an alternative to NE in whiter cases.
	Yellow Enamel (YE)	YE is designed to mimic discolored enamel.
Enamel	Trans Enamel (TE)	TE is the most translucent in ESTELITE ASTERIA. This shade is recommended as an alternative to NE in highly translucent cases.
	Occlusal Enamel (OCE)	OCE is recommended for the occlusal surface. Shading is optional sculptability to shape occlusal cusps and fissures.

INDICATIONS

- Direct anterior and posterior restorations including occlusal surfaces
- Direct bonded composite veneer
- Distal seal closure
- Repair of porcelain/composite

CONTRAINDICATIONS

ESTELITE ASTERIA contains methacrylic monomers. DO NOT use ESTELITE ASTERIA for patients allergic to or hypersensitive to methacrylate and related monomers or to any of the other ingredients.

PRECAUTIONS

- DO NOT use ESTELITE ASTERIA for any purposes other than those listed in these instructions. Use ESTELITE ASTERIA only as directed herein.
- ESTELITE ASTERIA is designed for sale and use by licensed dental care professionals only. It is not designed for sale or by non-dental care professionals.
- DO NOT use ESTELITE ASTERIA if the safety seals are broken or appear to have tampered with.
- IF ESTELITE ASTERIA causes an allergic reaction or hypersensitivity, discontinue its use immediately.
- Use excavation gloves (plastic, vinyl or latex) at all times when handling ESTELITE ASTERIA to avoid the possibility of allergic reactions from methacrylic monomers. Note: Certain substances/materials may penetrate through examination gloves. IF ESTELITE ASTERIA comes in contact with the examination gloves, remove and dispose of the gloves, and wash hands thoroughly with water as soon as possible.
- Avoid contact of ESTELITE ASTERIA with eyes, mucosal membrane, skin and clothing. IF ESTELITE ASTERIA comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
- IF ESTELITE ASTERIA comes in contact with the mucosal membrane, wipe the affected tooth immediately, and thoroughly flush with water after the restoration is completed.
- IF ESTELITE ASTERIA comes into contact with the skin or clothing, immediately saturate the area with an alcohol soaked cotton swab or gauze.
- Do not attempt to treat high blood pressure or other acute conditions.
- ESTELITE ASTERIA should not be ingested or aspirated. Ingestion or aspiration may cause serious injury.
- Do not allow the unintentional ingestion of ESTELITE ASTERIA, do not leave it unattended with the reach of patients and children.
- Clean the placement instruments and brushes with alcohol, glasser use.
- Wear using a light-curing unit, protective eye shields, after use of goggles should be worn at all times.
- 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 cure.

INDICATIONS FOR FILLING AND CURING

ESTELITE ASTERIA is designed to be cured by either a halogen, LED or Plasma Arc light with a wavelength of 400-500 nm. Be sure to light-cure ESTELITE ASTERIA extra-orally and check the time needed for complete hardening of ESTELITE ASTERIA 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 ²)	Curing time (Seconds)	Increment depth (mm) ¹⁾			
			A1B, A2B, A3B, A3.5B, B3B, B4,	NE, WE, YE, TE, OCE	A4B	A4B
Halogen	400	10	1.7	—	—	—
		20	2.0	2.0	1.7	—
		30	2.1	2.1	1.8	—
LED	400	10	1.7	—	—	—
		20	2.0	2.0	1.7	—
		30	2.2	2.2	1.8	—
Plasma Arc	950	6	1.9	1.8	1.8	

- Increment depth was determined on the basis of test results performed in accordance with section 7.10 "depth of cure" of ISO4049.
- Curing time should be at least 20 seconds.

SPECIAL NOTES FOR THE USE OF PLT

- PLTs are designed for single patient use only. To avoid cross infection, DO NOT re-car and/or reuse the PLT on one patient after the indicated date of expiration on the syringe or PLT package.
- Dispensers are not provided for ESTELITE ASTERIA. Use a dispenser that fits the PLT of ESTELITE ASTERIA. For proper use and proper disinfection, see manufacturer's instructions.
- Use light, controlled pressure to prevent any continued extrusion of material following pressure release.

STORAGE

- Store ESTELITE ASTERIA at temperatures between 0 - 25°C (32 - 77°F).
- AVOID direct exposure to light and heat.
- DO NOT use ESTELITE ASTERIA after the indicated date of expiration on the syringe or PLT package.

DISPOSAL

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

CUSTOM SHADE GUIDE

See the instructions for ESTELITE ASTERIA Custom Shade Guide prior to use.

CLINICAL PROCEDURE

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

Shade Selection

Select the appropriate shade of ESTELITE ASTERIA using the custom shade guide prepared in advance.

- Complete the shade selection within 5 minutes; teeth become whiter when dehydrated.
- Lightness (color value) is the primary important shade selection.
- Use whitened tooth, select shade 1-2 levels above a few seconds after the completion of whitening. Whiteness tends to become slightly darker with the elapse of time.
- Please see the table depicting the shade of tint (SHADE).

Isolation

A rubber dam is the preferred method of isolation.

Cavity Preparation

Prepare the cavity and rinse with water. Add beads to the enamel margins of anterior preparations (class III, IV, V), bevels aside in erasing demarcations between the cavity margins and the restoration, thereby enhancing both esthetics and retention.

scaled-off (undisturbed) level may be desirable depending on the esthetics and retention.

- In the 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 or thoroughly with water.

In the case of porcelain/composite repairs, remove the surface with a bur or a diamond point to prepare the area for adhesion; apply phosphoric acid gel for cleaning; rinse thoroughly with water; air dry thoroughly and treat with a silane coupling agent according to manufacturer's instructions.

5. Pulp Protection

Protect the pulp appropriately, if the cavity is in close proximity to the pulp. In the case of pulp exposure, apply calcium hydroxide for pulp capping. DO NOT USE EUGENOL-BASED MATERIALS to protect the pulp as these materials will inhibit curing of ESTELITE ASTERIA.

Bonding System

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

Finishing

- PLT Please read SPECIAL NOTES FOR THE USE OF PLT before use.
- Load the PLT into a dispenser that fits the PLT.
- Remove the PLT cap.
- Extrude the paste directly into cavity or indirectly on the mixing pad.

2. SYRINGE

Remove the syringe cap. Extrude the paste onto a mixing pad by turning the handle clockwise. After dispensing, turn the handle counterclockwise by a half to full turn to reduce the residual pressure inside the syringe and after the restoration.

DO NOT apply unnecessary force to the syringe immediately after removing from the refrigerator.

8. Filling and contouring

Fill the cavity incrementally. Increments should not exceed the indicated curing depth (please refer to the aforementioned table).

In the case that characterization is required, tints (such as ESTELITE COLOR) can be used. Apply the tint according to manufacturer's instructions.

DO NOT mix ESTELITE ASTERIA with other brands of composite resin to avoid incomplete cure or entrapment of air bubbles. In order to avoid air bubbles entrapment, DO NOT mix ESTELITE ASTERIA with another shade of the paste.

9. Curing

Light-cure each increment for at least the indicated time (please see aforementioned table), keeping the curing light tip within a distance of 2 mm from the increment.

If other brands of composite resins are layered over the cured composite, follow its manufacturer's instructions.

10. Finishing

Shape and polish the restoration. For finishing, use finishing discs and/or fine finishing diamond points. Use metal finishing strips or vinyl polishing strips for proximal surfaces.

For polishing, polish with rubber points or any suitable polishing tool. For final polishing, use felt discs or cotton wheels with polishing paste, or suitable polishing tools.

Instruct the patient adequately on the maintenance of the restoration after treatment.

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СПЕЦИАЛНИ УКАЗАНИЯ ОТНОСНО УПОТРЕБАТА НА PLT.

1) PLT са предназначени за употреба само за един пациент. За да избегнете кръстосана инфекция, след дозирание на материала за пациента не загваряйте и/или не използвайте отново PLT наръчката.

2) ESTELITE ASTERIA не се достига с диспенсер. Използвайте диспенсер, който е подходящ за PLT на ESTELITE ASTERIA. Вж. инструкциите на производителя за употреба правилната употреба и дезинфекция.

3) Използвайте само вие, контролирайте нивото на нивото на материала и използвайте екструдирания материал след осъществяване на патента.

СЪВЪРШЕНИЕ

1) Съхранявайте ESTELITE ASTERIA при температура между 0 и 25°C (32 - 77°F).

2) ИЗБЕЖАВАЙТЕ излагане на пряка слънчева светлина и топлина.

3) НЕ използвайте ESTELITE ASTERIA след изтичане на посочения на опаковката на шприцата срок на годност.

4) SYRINGE En cas de contact d'ESTELITE ASTERIA avec les yeux, les rincer abondamment à l'eau et contacter immédiatement un ophtalmologiste.

- En cas de contact d'ESTELITE ASTERIA avec les muqueuses, essayer immédiatement la zone à l'aide d'un tampon de coton ou d'une gaze imbibée(e) d'alcool.

- En cas de contact d'ESTELITE ASTERIA avec la peau ou un vêtement, tremper immédiatement la zone à l'aide d'un tampon de coton ou d'une gaze imbibée(e) d'alcool.

5) SYRINGE Demander au patient de se rincer la bouche immédiatement et le traitement.

