

1 Intended use

Intended purpose

Dental bonding

Use

For dental use only.

Description

Adhese® Universal DC is a dual-curing, single-component dental adhesive for enamel and dentin that is compatible with all etching techniques (self-etch, selective enamel-etch, etch & rinse techniques).

The areas of application include adhesive cementation of indirect restorations and direct restorative procedures.

a. Pure self-curing of Adhese Universal DC (without light-curing)

- Adhesive cementation of indirect restorations and endodontic posts using Variolink® Esthetic DC with all etching techniques.
- Adhesive cementation of indirect restorations and endodontic posts using light- and dual-curing luting composites with the etch & rinse technique.

b. Light-curing of Adhese Universal DC at 500 to 1,400 mW/cm²

- Adhesive cementation of indirect restorations with light- and dual-curing luting composites
- Direct-placed reconstructive build-ups and core build-ups with light-, self- and dual-curing composites
- Direct-placed light-curing composites and compomer restorations
- Repairs of fractured composite and compomer restorations
- Desensitization of hypersensitive cervical areas (Note: Provide additional cooling with an air syringe when applying the product.)
- Sealing of prepared tooth surfaces before temporary/permanent cementation of indirect restorations

c. When Adhese Universal DC is light-cured using

Bluephase® PowerCure in the 3sCure curing mode

- Only restorations in the posterior region of permanent dentition (Class I and II, including the replacement of individual cusps) when light-cured from the occlusal aspect.

Adhese Universal DC is available in Free Stand® Single Dose units. The applicator is coated with co-initiators required for the self-curing reaction. The initiator and adhesive are mixed together by dipping the applicator into the Single Dose unit containing the liquid Adhese Universal DC.

The applicators are available in two different sizes:

- Regular for cavities, crown preparations, etc.
- Small/endo for root canals and micro-preparations.

Indication

- Missing tooth structure
- Partial edentulism

Adhese® Universal DC

EN Instructions for Use	FI Käyttöohjeet
– Dual-curing single-component dental adhesive	– Kaksoiskovetteinen, yksikomponenttinen sidosaine
DE Gebrauchsinformation	NO Bruksanvisning
– Dualhärtendes Einkomponenten-Dentaladhäsiv	– Dualherdende enkomponents-dentaladhesiv
FR Mode d'emploi	NL Gebruiksaanwijzing
– Adhésif dentaire monocomposant à photopolymérisation duale	– Duaal uithardend eencomponentadhesief voortandheelkundig gebruik
IT Istruzioni d'uso	EL Οδηγίες Χρήσεως
– Adesivo dentale monocomponente ad indurimento duale	– Οδοντιατρικός συγκολλητικός παράγοντας, διπλού πολυμερισμού, ενός συστατικού
ES Instrucciones de uso	TR Kullanma Talimatı
– Adhesivo dental monocomponente de polimerización dual.	– Çift sertleşen tek bileşenli dental adeziv
PT Instruções de Uso	RU Инструкция по применению
– Adesivo dental dual monocomponente	– Однокомпонентный стоматологический адгезив двойного отверждения

Contraindications

- Direct pulp capping.
- Do not use Adhese Universal DC if the patient is known to be allergic to any of the materials’ ingredients or if the stipulated working technique cannot be employed.

Limitations of use

Do not use Adhese Universal DC as a primer for ceramic restorative materials. A suitable ceramic primer must be used (e.g. Monobond Etch & Prime®).

Side effects

In rare cases, components of Adhese Universal DC may lead to sensitization. In such cases, Adhese Universal DC should no longer be used.

Interactions

- Peroxide-based bleaching agents and disinfectants may inhibit the polymerization of adhesives. Such materials must not be used ≤ 14 days prior to the application of Adhese Universal DC.
- Phenolic substances (e.g. eugenol) may inhibit the polymerization of Adhese Universal DC.
- Before any treatment with Adhese Universal DC, completely rinse off all iron- and aluminium-based styptic agents with water.
- Fluoridation agents must not be used prior to the application of Adhese Universal DC.

Composition

HEMA, MDP, Bis-GMA, D3MA, ethanol, methacrylate-modified polyacrylic acid, silicon dioxide, potassium hydroxide and camphorquinone.

2 Application

2.1 Procedure for indirect and direct restorations

2.1.1 Isolation

Adequate relative or absolute isolation using suitable auxiliaries, such as OptraGate® or OptraDam Plus, is required.

2.1.1 Pulp protection / cavity liner

The 3sCure curing mode must not be used for restorations in areas close to the pulp. In very deep cavities, areas close to the pulp should be selectively coated with a calcium hydroxide liner (e.g. ApexCal®) and subsequently covered with a pressure-resistant cement (e.g. glass ionomer cement).

2.1.3 Conditioning with phosphoric acid gel

The bond to enamel can be improved by selectively etching the enamel or by applying the etch & rinse technique. Unprepared enamel surfaces must always be conditioned with phosphoric acid gel (e.g. Total Etch). Please observe the instructions for use for the phosphoric acid gel.

a. Selective enamel-etch technique

Apply phosphoric acid gel (e.g. Total Etch) onto the enamel and allow it to react for 15–30 s. Then rinse thoroughly with a vigorous stream of water for at least 5 s and dry with oil- and water-free compressed air until the etched enamel surfaces appear chalky white.

b. Etch & rinse technique

Apply phosphoric acid gel (e.g. Total Etch) onto the prepared enamel first, and then onto the dentin. The etchant should be left to react on the enamel for 15–30 s and on the dentin for 10–15 s. Then rinse thoroughly with a vigorous stream of water for at least 5 s and dry with oil- and water-free compressed air until the etched enamel surfaces appear chalky white.

2.1.4 Activation of the Free Stand® Single Dose

- Remove the foil lid.
- Remove the green applicator brush from its chamber and dip into the unit containing the adhesive.
- Mix the adhesive with the co-initiators for 5 s by twisting the applicator. The flocking of the applicator shows a uniform yellow colour when it is completely mixed. If this is not the case, repeat the mixing procedure.
- Once activated, the adhesive can be used for approx. 120 s.

Note:

Adhese Universal DC Free Stand® in single dose delivery form must not be used for more than one patient due to hygienic reasons (prevention of cross-contamination between patients). Dispose of residual activated Adhese Universal DC material after application!

2.1.5 Application of the adhesive

- Starting with the enamel, completely coat the tooth surfaces to be treated with Adhese Universal DC.
- The adhesive must be scrubbed into the tooth surface for at least 20 s. This time must not be shortened. Applying the adhesive on the tooth surface without scrubbing is inadequate.
- Disperse Adhese Universal DC with oil- and water-free compressed air until a glossy, immobile film layer results.

Important information:

- Avoid pooling, as this can compromise the accuracy of fit of the restoration.
- Exposure to intensive light should be avoided during application.
- Prevent the contamination of the applicator with blood, saliva, sulcus fluid or water during application.
- Do not dip the green applicator more than two times into the unit with the adhesive.

2.1.6 Curing the adhesive

Self-curing Adhese Universal DC

Adhese Universal DC can be used in the pure self-curing mode in conjunction with suitable self- and dual-curing core build-up and luting composites, e.g. Variolink Esthetic DC, in the following cases:

Application / Indication	Curing mode of the luting or core build-up composite	Etching technique	
		Etch & rinse	Self-etch Selective enamel etching
Adhesive cementation of indirect restorations and endodontic posts	Light- or dual-curing	✓	✓
	Self-curing	✓	Only in combination with Variolink Esthetic DC

Light curing Adhese Universal DC

Adhese Universal DC must be light-cured in the following cases:

Application / Indication	Curing mode of the core build-up or restorative composite material	Etching technique	
		Etch & rinse	Self-etch Selective enamel etching
Direct restorations and core build-ups	Light- or dual-curing	✓	✓
Sealing, desensitization, immediate dentin sealing	—	✓	✓

Adhese Universal DC can be light-cured for 10 s at a light intensity of 500 to 1,400 mW/cm². In the fabrication of Class I and II restorations, Adhese Universal DC can be light-cured in only 3 s from the occlusal aspect at a light intensity of 2,700 to 3,300 mW/cm² (e.g. using Bluephase PowerCure).

The instructions for use of the curing light must be observed.

Light intensity (mW/cm²)	Exposure times
500–900	10 s
900–1,400	10 s
1,800–2,200	—
2,700–3,300	3 s

Safety note

- Avoid direct exposure of the gingiva, mucous membrane or skin to the light emitted by the curing light.
- The 3sCure mode must not be used in case of caries profunda and very deep cavities.

2.1.7 Application of the restorative or luting composite

- Proceed according to the instructions for use of the restorative and/or luting composite used.

2.2 Procedure for intraoral repairs of fractured composite fillings/ composite restorations with light-curing materials

- Roughen the surface to be repaired using diamond finishers, thoroughly clean with water spray and dry with oil- and water-free compressed air.
- Proceed according to the direct application for Adhese Universal DC.

2.3 Procedure for the conditioning of Tetric® CAD restorations

- Proceed according to the instructions for use for Tetric CAD.

3 Safety information

- Direct application of the luting composite to a preparation pre-treated with adhesive may lead to an acceleration of the curing process and affect the fitting accuracy of the restoration.
- Adhese Universal DC is irritant. Avoid contact with the skin, mucous membrane and eyes.

PL Instrukcja stosowania

Jednoskładnikowy materiał łączący o podwójnym mechanizmie utwardzania

SV Bruksanvisning


Dual-härdande en-komponents dentaladhesiv

DA Brugsanvisning

Dualhærdende, enkelt-komponent dental adhæsiv


Rx ONLY

CE 0123



Manufacturer:
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- After skin contact, immediately rinse with copious amounts of water.
- If the material should accidentally come in contact with the eyes, immediately rinse with copious amounts of water and consult a physician / ophthalmologist.
- In rare cases, contact with the skin may cause sensitization to the ingredients.
- Commercial medical gloves do not provide protection against the sensitizing effects of methacrylate.
- In the case of serious incidents related to the product, please contact Ivoclar Vivadent AG, Bendererstrasse 2, 9494 Schaan/Liechtenstein, website: www.ivoclarvivadent.com, and your responsible competent authority.
- The current Instructions for Use are available in the download section of the Ivoclar Vivadent AG website (www.ivoclarvivadent.com).
- The current Summary of Safety and Clinical Performance (SSCP) can be found in the download section of the Ivoclar Vivadent AG website (www.ivoclarvivadent.com).

Warnings

Warnings for phosphoric acid gel

Phosphoric acid gel is corrosive. Avoid contact with the eyes, mucous membrane and skin (goggles are recommended for both patients and operators). If the material should accidentally come in contact with the eyes, immediately rinse with copious amounts of water and consult a physician / ophthalmologist.

Disposal information

Remaining stocks must be disposed of according to the corresponding national legal requirements.

4 Shelf life and storage

- Storage temperature 2–28 °C (36–82 °F)
- Non-observance of the storage temperature indicated may impair the functionality of the product.
- Do not use the product after the indicated date of expiration.
- Expiration date: See note on packaging

5 Additional information

Keep material out of the reach of children!

Not all products are available in all countries.

The material has been developed solely for use in dentistry. Processing should be carried out strictly according to the Instructions for Use. Liability cannot be accepted for damages resulting from failure to observe the Instructions or the stipulated area of use. The user is responsible for testing the products for their suitability and use for any purpose not explicitly stated in the Instructions.

Deutsch

1 Bestimmungsgemässe Verwendung

Zweckbestimmung

Kleben dentaler Restaurationen

Verwendung

Nur für den dentalen Gebrauch!

Beschreibung

Adhese® Universal DC ist ein dualhärtendes Einkomponenten-Dentaladhäsiv für Schmelz und Dentin in Kombination mit allen Ätztechniken (im Self-Etch-, selektiver Schmelzätzung- und Etch & Rinse-Verfahren). Anwendungsgebiete sind die adhäsive Befestigung indirekter Restaurationen und die direkte Füllungstherapie.

a. Reine Selbsthärtung von Adhese Universal DC (ohne Lichthärtung)

- Adhäsive Befestigung indirekter Restaurationen und Wurzelstifte mit Variolink® Esthetic DC mit allen Ätztechniken.
- Adhäsive Befestigung indirekter Restaurationen und Wurzelstifte mit licht- und dualhärtenden Befestigungscompositen im Etch & Rinse-Verfahren.

b. Belichtung von Adhese Universal DC bei 500 bis 1400 mW/cm²

- Adhäsive Befestigung indirekter Restaurationen mit licht- und dualhärtenden Befestigungscompositen.
- Direkte Aufbauauffüllungen und Stumpfaufbauten mit licht-, selbst- und dualhärtenden Compositen.
- Direkte, lichthärtende Composite- und Compomer-Restaurationen.
- Reparatur frakturierter Composite- und Compomer-Restaurationen.
- Desensibilisierung empfindlicher Zahnhälse. (Hinweis: Anwendung unter zusätzlicher Kühlung mit Luftspray.)
- Versiegelung präparierter Zahnoberflächen vor der temporären/ definitiven Befestigung indirekter Restaurationen.

c. Belichtung von Adhese Universal DC mit Bluephase® PowerCure im 3sCure-Belichtungsprogramm

- Ausschliesslich für Füllungen im Seitenzahnbereich des bleibenden Gebisses (Klassen I und II, einschliesslich Ersatz einzelner Hocker) bei okklusaler Belichtung.

Adhese Universal DC ist in einer Free Stand® Single Dose erhältlich. Der Applikator ist mit den für die Selbsthärtung benötigten Co-Initiatoren beschichtet. Durch das Eintauchen des Applikators in den Single Dose Behälter mit Adhese Universal DC Flüssigkeit werden Initiatoren und Adhäsiv miteinander gemischt. Die Applikatoren sind in zwei Grössen erhältlich:

- Regular für Kavitäten, Kronenpräparationen etc.
- Small/Endo für Wurzelkanäle und Mikropräparationen

Indikation

- Fehlende Zahnhartsubstanz
- Partielle Zahnlosigkeit