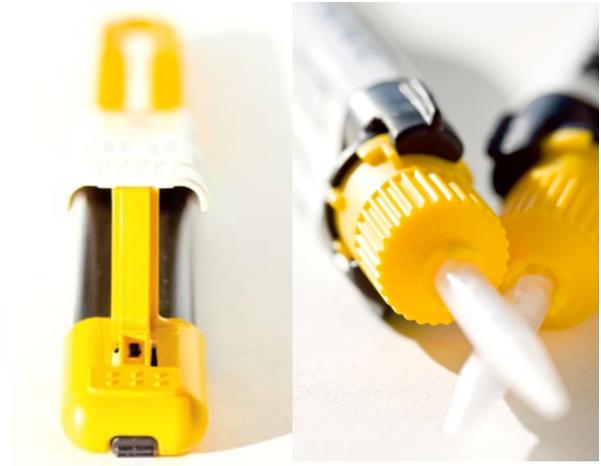


FAQs - RelyX™ Unicem 2 Automix/Clicker



Generals

1. What clinical data is available on RelyX Unicem 2 Automix/Clicker?

RelyX™ Unicem 2 Automix/Clicker were tested for biocompatibility before release. RelyX™ Unicem 2 Automix is successfully on the market since September 2010. RelyX Unicem 2 Automix and Clicker have both been tested clinically before launch by more than 120 dentists in the US and Europe who reported very positive results on handling and flow properties and experienced none to very low numbers of post-operative hypersensitivities.

The low post-operative sensitivity rate was also confirmed in a controlled clinical trial for RelyX Unicem 2 Automix. There were zero cement related hypersensitivities found (Source: Baseline report, May 2010, Dr. Dr. A. Syrek)

2. Do RelyX™ Unicem cement in the Aplicap™ / Maxicap™ and RelyX Unicem 2 Automix/Clicker™ have the same chemical composition?

RelyX Unicem 2 Automix/Clicker is based on the same proven and patented chemistry of RelyX Unicem Aplicap/Maxicap and previous Clicker. The RelyX Unicem adhesion monomer (a phosphoric acid methacrylate), the patented initiator system, and the special filler technology providing the unique neutralization behaviour remain unchanged.

Several modifications to that system were made to further improve material properties and to achieve reliable material quality when automatically mixed in a mixing tip. An additional monomer and a new rheology modifier were added to the mixture and we optimized the processing of our filler particles. All that leads to a formulation optimized for the new delivery and displays increased mechanical properties and excellent overall adhesion performance.

RelyX Unicem 2 Automix and Clicker are slightly more flowable than the original formulation. The improved flow properties described also lead to easier hand-mixing, which was confirmed by our customers.

What are the differences between RelyX Unicem 2 Automix and RelyX Unicem 2 Clicker?

RelyX Unicem 2 Automix and RelyX Unicem 2 Clicker are identical in chemical formulation.

What are the differences to RelyX Unicem Aplicap?

RelyX Unicem Aplicap is the most proven self-adhesive resin cement in the market. It is a powder/liquid formulation in single use capsule delivery. The new generation builds on this proven chemistry as described above.

3. RelyX Unicem 2 Automix/Clicker: Indications

- Final cementation of all-ceramic, composite, or metal inlays, onlays, crowns and bridges; 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis)
- Final cementation of posts and screws
- Final cementation of all-ceramic, composite, or metal restorations on implant abutments

4. Why are RelyX Unicem and Unicem 2 cements not indicated for cementing veneers?

RelyX Unicem is a dual curing cement and, once mixed, there is a limited amount of working time. It could be difficult for the dentist to load up multiple veneers and seat them properly before the working time is up. RelyX Unicem/Unicem 2 cements do not contain aromatic amine initiator components that might lead to material discoloration.

For cementing veneers, the light cured RelyX™ Veneer cement has been specifically designed, and perfectly complements RelyX Unicem/Unicem 2 cements.

Automix Delivery System

5. RelyX Unicem 2 Automix: Which mixing tips are to be used for which application?

The regular mixing tip is suitable for crown and bridge cases. The mixing tip wide has to be used in combination with either intaloral tip or endo tip.

The intra-oral tip is recommended for syringing material directly into patient's mouth, e.g. inlay preparations. The angulation allows easy application also in dorsal regions. The thin endo-tip fits best for post cementation in root canals (e.g. RelyX Fiber Post).

6. Do I need to recap the automix syringe after use?

Leave the used mixing tip on the automix syringe as a cap until the next application. The original sealing cap must not be reused to close the syringe to avoid cross contamination and/or the inclusion of air bubbles into the material.

7. How many applications are possible with the material from one automix syringe?

According to clinical evidence the amount of cement in one syringe should be sufficient for about 16 applications (in a typical mix of all kinds of restorations).

8. How much material remains in the mixing tip?

RelyX Unicem 2 Automix uses mixing tips with 8 spirals. Only 0,357g of material remains in the tip. Competitors using mixing tips with 12 spirals have about 0,427g of

waste. Be aware that you also have material loss when using hand-mixed cements. Compared to hand-mixed materials you will probably be able to save material due to direct and precise dosing.

9. Can the RelyX Unicem 2 Automix syringe be disinfected?

We recommend the use of commonly available hygienic protective covering, e.g. plastic film, to avoid any contamination of the RelyX Unicem 2 Automix syringes during the treatment.

A contaminated RelyX Unicem 2 Automix syringe can be cleaned with agents commonly used in the dental practice.

Use a cloth soaked in a disinfectant to disinfect the device.

10. RelyX Unicem 2 Automix/Clicker: Indications

- Final cementation of all-ceramic, composite, or metal inlays, onlays, crowns and bridges; 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis)
- Final cementation of posts and screws
- Final cementation of all-ceramic, composite, or metal restorations on implant abutments

11. Why are RelyX Unicem and Unicem 2 cements not indicated for cementing veneers?

RelyX Unicem is a dual curing cement and, once mixed, there is a limited amount of working time. It could be difficult for the dentist to load up multiple veneers and seat them properly before the working time is up. RelyX Unicem/Unicem 2 cements do not contain aromatic amine initiator components that might lead to material discoloration.

For cementing veneers, the light cured RelyX™ Veneer cement has been specifically designed, and perfectly complements RelyX Unicem/Unicem 2 cements.

Clicker Delivery System

12. Can the RelyX Unicem 2 Clicker be disinfected?

A contaminated RelyX Unicem 2 Clicker can be cleaned with agents commonly used in the dental practice.

Use a cloth soaked in a disinfectant to disinfect the device.

13. How many applications are possible with the material from one Clicker device?

As before, the 11g Clicker contains 80 “clicks”, an equivalent to approx 40 crown cementations.

Clinical questions

14. How should I dry the tooth prior to cementing my restoration with RelyX Unicem or Unicem 2 cements?

Lightly dry in only 2-3 second intervals with oil-free and anhydrous air, or use cotton gauze or foam pellets to dry off excess water. Do not over dry! The tooth should be just dry enough that the surface has a slightly glossy appearance. As is the case with any fixation cement, over drying can lead to post-operative sensitivity.

15. How do I prepare the root canal before cementation of a post with RelyX Unicem or Unicem 2 cements?

We recommend the use of a rubber dam during the cementation of posts. Remove the existing (Guttapercha) root filling (leave 4 mm apically) and clean the root canal with a 2.5 - 5.25% sodium hypochlorite solution (NaOCl). Rinse immediately with water and dry with paper points. Do not overdry.

16. May I use desensitizing agents before cementing restorations with RelyX Unicem or Unicem 2 cements?

The unique chemistry of RelyX Unicem/Unicem 2 cement demineralizes and penetrates into the tooth surface without utilizing a separate acid etching step. This greatly reduces the potential for patient tooth sensitivity when compared to a typical total-etch resin cement system. Therefore, the use of an additional desensitizing step has NOT been deemed beneficial. We recommend cleaning the prepared tooth with an aqueous pumice slurry and water as the final treatment before cementing the restoration with RelyX Unicem/Unicem 2 cements.

17. Will fit checker materials have an affect on the bond strength of the cement?

Yes. Contamination of the tooth surface with fit checker material could be detrimental to any bond. If a fit checker or any oil-based product is used during try-in use, an aqueous pumice slurry and water spray rinse is recommended to ensure a clean tooth surface prior to cementation.

18. How should the restoration be pre-treated when using RelyX Unicem or Unicem 2 self-adhesive resin cements?

In general, follow the instructions of the manufacturer of the restoration for adhesive cementation. When no information is given, 3M ESPE recommends the following:

Material type	Pretreatment	Examples
Metal, PFM	Sand blasting ($\leq 50 \mu\text{m}$), clean with Ethanol	IPS d.SIGN
Glass ceramic etchable	Etching with hydrofluoric acid, Followed by a Silanisation agent	IPS Empress, Empress 2, e.max
Zirconia non-etchable, high strength	Sand blasting ($\leq 50 \mu\text{m}$), clean with Ethanol <i>Alternative:</i> Silicatisation with Rocatec and Silanisation	Lava Crowns & Bridges
Alumina non-etchable, high strength	Sand blasting ($\leq 50 \mu\text{m}$), clean with Ethanol <i>Alternative:</i> Silicatisation with Rocatec and Silanisation	Procera AllCeram
Composite	Sand blasting, clean with Ethanol	Sinfony, Artglass, Belleglass
Fiber post	Clean with Ethanol	RelyX Fiber Post

For additional details please refer to the instructions for use.

19. How should I pretreat my chairside CAD/CAM restoration?

The materials used with chairside CAD/CAM systems (e.g. CEREC, Sirona; E4D, D4D) are either etchable glass ceramics (e.g. Vitablocs® Mark II, VITA; e.max CAD, Ivoclar Vivadent) or composite material (e.g. Paradigm™ MZ100, 3M ESPE). For detailed pretreatment recommendations see previous question.

An important consideration for using RelyX Unicem/Unicem 2 cements for bonding chairside CAD/CAM restorations is to make sure that the tooth surface is completely clean prior to placing the cement. The scanning process for some systems (e.g. CEREC, Sirona) requires that a scan powder or spray with or without a separate liquid adhesive be placed on the tooth to obtain a good digital image. It is imperative that the scan powder/spray be completely removed from the tooth surface prior to placement of the restoration.

RelyX Unicem/Unicem 2 cements must be able to directly interact with the clean tooth surface in order to demineralize the surface and penetrate into the tooth. Any residue from the liquid or powder may affect the bond of the RelyX Unicem/Unicem 2 cements to the tooth. This may result in marginal staining or failure of the restoration.

A simple water spray or rinse may not completely remove the residue. It is advisable to physically remove the powder/liquid residue from the tooth by brushing the surface with aqueous pumice slurry followed by a thorough water rinse.

20. Are RelyX Unicem and Unicem 2 cements compatible with core build-up materials?

RelyX Unicem cement provides a secure bond to all types of core build-up materials. However, composite core build-up materials are the preferred material type with respect to its physical properties and aesthetics and required in combination with fiber reinforced composite posts.

The surface of the core build-up material should be roughened. Use alcohol to clean and dry.

21. How can occasional marginal discoloration be avoided?

1. Do not use iron-containing liquids, e.g. astringents, retraction solution with translucent all-ceramic crowns. A gray discoloration may develop underneath the translucent restoration a few weeks after cementation. Do not use ferrous astringents at the impression appointment or seating appointment.
2. After final cleaning with aqueous pumice slurry and water spray, avoid using desensitizers, disinfectants, astringents, hydrogen peroxide (H₂O₂), dentin sealants, and rinsing solutions containing EDTA, etc. These treatments can leave chemical residues which may have a detrimental effect on the bond strength and setting reaction of the cement.
Hydrogen peroxide (H₂O₂), is a strong oxidizing agent that interacts with chemical initiating systems. Hydrogen peroxide is hardly removed from the tooth surface by water spray. Generally, its use should be avoided with any resin cement.
3. Make sure to pre-treat the restoration as described in the RelyX Unicem cement instructions for use. For details see also question 18.

22. Are try-in pastes available for RelyX™ Unicem and Unicem 2 cements?

Yes, there are RelyX Try-In Pastes, available individually or as part of the RelyX Veneer cement intro kit. They are designed to fit both RelyX Unicem cements and RelyX Veneer cement shades.

23. Does 3M ESPE recommend selective enamel etching for Maryland and inlay/onlay bridges?

Indications such as Maryland and inlay/onlay bridges (resin bonded bridges) demand especially high adhesive bond strength. Regardless of the manufacturer of the cement and restoration, these indications may be exposed to a higher risk of decementation. Abutment teeth must have an adequate enamel surface for bonding. Therefore prepare retentive elements such as cingular rests and/or approximal grooves. Etch the enamel surface of the cavity with 37% phosphoric acid for 15-20 sec. In the case of exposed dentin, make sure to selectively etch the enamel to avoid post-operative sensitivity.

24. Can a separate etching help to increase bond strength in general?

RelyX Unicem/Unicem 2 cements show good bond strength to enamel and very high bond strength to dentin without any pretreatment. If enamel is selectively etched the bond strength to enamel can be improved to a degree. However, etching of dentin does NOT increase bond strength, whereas it generates the risk of post-operative sensitivities and microleakage. Therefore, if selective etching of enamel is desired, care ought to be taken not to etch adjacent dentin.

Material Properties

25. What is the shelf life of RelyX Unicem 2 Automix/Clicker?

The material leaves our factory with a shelf-life of 18 months. Store RelyX Unicem 2 Automix and Clicker in the foil pouch at 15°-25 °C/59°-77 °F. After removal from the pouch the product should be used within 6 months and before the lapse of the expiration date.

Constant exposure to high humidity accelerates the setting and must be avoided.

26. What is the working time of RelyX Unicem 2 Automix and Clicker?

Working time from start of mixing is 2:00 minutes

The processing and setting times depend on the ambient and oral temperature. The two minutes are based on conditions relevant for practice. As is the case with all composite cement, the setting of RelyX Unicem 2 Automix/Clicker cement slows down significantly at room temperature.

RelyX Unicem 2 Automix/Clicker is a dual-curing cement and therefore also sensitive to natural or artificial light. The working time is significantly reduced during application under operating lights!

	min:sec
Working time from start of mixing:	02:00
Light curing:	
– single surface, from occlusal	00:20
– any other surface additional	00:20
RelyX Fiber Post posts, from occlusal	00:40
Self-curing:	
Polymerization start after start of mixing	02:30
Polymerization end after start of mixing	06:00

27. Is there a recommended waiting time before light curing RelyX Unicem/Unicem 2 cements?

No. In contrast to certain self-adhesive resin cements by other manufacturers for which some waiting time is recommended, RelyX Unicem/Unicem 2 cements can be light-cured immediately and high bond strengths will be achieved. The reason lies within the highly efficient and fast initiator system in combination with the unique adhesive technology.

28. Why has RelyX Unicem Aplicap/Maxicap also been released for the cementation of Maryland bridges?

3M ESPE tested RelyX Unicem cements in comparison to state of the art resin cements that are released for those indications. RelyX Unicem cements achieved comparable or higher adhesion when enamel was etched and the restoration pretreated according to the instructions for use.

Selective enamel etching increases the surface available for bonding, necessary for those special indications. A separate application of an adhesive/bonding agent is not necessary, RelyX Unicem cements are self-adhesive.

29. Will RelyX Unicem/Unicem 2 cements flow sufficiently when the restoration is seated?

The new generation RelyX Unicem 2 Automix/Clicker is slightly more flowable than RelyX Unicem.

All RelyX Unicem cements exhibit a so-called “thixotropic” behavior. They flow easily under pressure yet increase in viscosity when left undisturbed. This means that when placing a restoration with the usual pressure a low film thickness and an exact placement is achieved. The benefit of higher viscosity in the absence of pressure is that RelyX Unicem cements stay put. They do not flow away from the prepared tooth, restoration or instrument and makes excess removal easier

30. What are the major mechanical characteristics?

Properties	RelyX™ Unicem 2 Automix/Clicker (Ic)
Flexural strength [MPa]	99
Compressive strength [MPa]	291
Modulus of elasticity [GPa]	6.6
Surface hardness [MPa]	190
Film thickness [µm]	13
Water sorption [µg/mm ³]	30
Solubility [µg/mm ³]	0
Expansion [%]	0.63