RelyX[™] Unicem 2 Automix

Self-Adhesive Resin Cement



Technical Data Sheet



54800/IAA222

Introduction

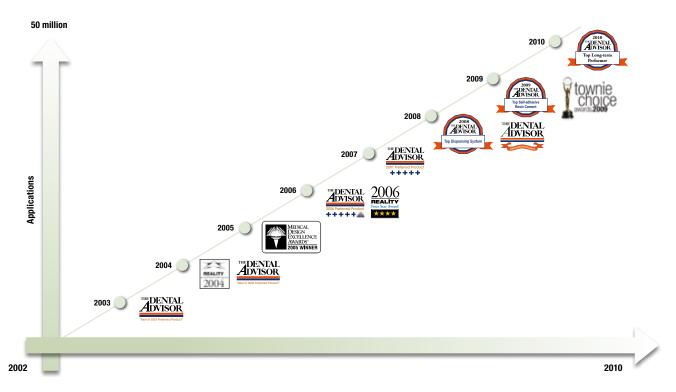
RelyX[™] Unicem 2 Automix Self-Adhesive Resin Cement represents the next generation of self-adhesive resin cements.

This newcomer is based on the same chemistry as RelyX[™] Unicem Self-Adhesive Resin Cement, the most clinically proven self-adhesive resin cement worldwide. This year it received the "2010 Top Long-term Performer" award by THE DENTAL ADVISOR*, which is only one of many awards the cement has won.



*www.dentaladvisor.com

The improved formulation remains closely related to its predecessor, while offering even more convenience due to its automix delivery system. The syringe dispenses the ready-mixed cement using mixing tips offered in three different sizes: Mixing tips for standard applications, endo tips ensuring a safe and void-free procedure when working in the root canal and for the cementation of inlays and onlays, special intra-oral tips are available as well.



As with the 1st generation, the need for any pre-treatment of the tooth, such as etching or priming and bonding, is eliminated. The combination of proven technology with innovative features makes RelyX Unicem 2 Automix cement a convenient and powerful high performing product.

Product benefits at a glance:

Simplicity

- Ease of use delivery system
- Self-adhesive
- Dual-cure
- Moisture-tolerant
- Very easy removal of excess

Performance

- Very high bond strength on all substrates
- Low post-operative sensitivity
- Excellent mechanical properties
- Excellent color stability
- Long-term stability

2 Indications

RelyX[™] Unicem 2 Automix cement is indicated for the permanent cementation of:

- All-ceramic, composite or metal inlays, onlays, crowns and bridges
- Posts and screws
- · All-ceramic, composite or metal restorations to implant abutments
- 2- or 3-unit Maryland bridges and 3-unit inlay/onlay bridges*

*The high adhesive bond strength of RelyX Unicem 2 Automix cement allows for reliable and comfortable cementation of Maryland and inlay/onlay bridges For these indications, an additional enamel etching step is required to increase the available surface area for bonding.

3

Description of self-adhesive resin cements

Based on their chemical composition, resin cements are commonly used in dental cements.

These cements can be classified into two groups — adhesive and self-adhesive resin cements. Various pre-treatment steps (etching, priming, bonding) and the absolute exclusion of moisture (rubber dam) are necessary to successfully use adhesive resin cements. Therefore, adhesive cementation is much more technique sensitive than conventional cementation and the clinical success may be compromised by the technical challenges it imposes on the dentist. These drawbacks were resolved with the introduction of the first self-adhesive universal resin cement, RelyX[™] Unicem Self-Adhesive Resin Cement, in 2002.

The next generation RelyX Unicem 2 Automix cement raises the high standard even higher: very easy and convenient usage combined with outstanding bond strength and very good mechanical properties.

3.1 What's unique for RelyX Unicem 2 Automix Cement?

RelyX Unicem 2 Automix cement is based on the same proven and patented chemistry as RelyX[™] Unicem Aplicap[™]/Maxicap[™] Capsules and Clicker[™] Dispenser. The RelyX[™] Unicem adhesion monomer (a phosphoric acid methacrylate), the patented initiator system and the special filler technology providing the unique neutralization behavior remained unchanged.

Several modifications to that system were made to further enhance material properties and to achieve reliable material quality when automatically mixed in the 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 of that leads to a formulation optimized for the new syringe delivery and displays increased mechanical properties and excellent overall adhesion performance.

3.2 Chemical composition

Base paste	Catalyst paste
Methacrylate monomers containing phosphoric acid groups	Methacrylate monomers
Methacrylate monomers	Alkaline (basic) fillers
Silanated fillers	Silanated fillers
Initiator components	Initiator components
Stabilizers	Stabilizers
Rheological additives	Pigments
	Rheological additives

Setting reaction

The setting of RelyX[™] Unicem 2 Automix Self-Adhesive Resin Cement is the same as for RelyX[™] Unicem Self-Adhesive Resin Cement. The reaction is started by light and/or by a chemical reaction of the initiator system (dual cure). The setting reaction is a radical polymerization during which the single monomer molecules are chemically cross-linked to form a three-dimensional polymer network. Simultaneously, neutralization reactions take place, which are important for the long-term stability of the set RelyX Unicem 2 Automix cement.

4 Application

RelyX Unicem 2 Automix cement combines the simple handling of the Automix syringe with the performance and convenience known of RelyX Unicem cement.

The system includes three shades (translucent, A2 universal and A3 opaque) offered in a 8.5 g automix syringe. Mixing tips for standard application, angulated intra-oral tips and endo tips are available.

Convenient and easy to use:

- Convenient automix
- Optimal consistency for dispensing and seating
- Flexible dosing
- Time-saving

- Universal a versatile choice of tips allows easy application for different indications
- · Low risk of air bubbles and voids
- · Easy excess removal

4.1 The delivery system is highly accepted by dentists

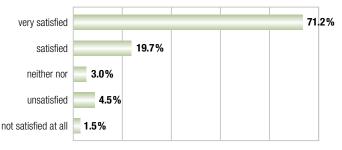


Fig. 1: Satisfaction level regarding delivery system. Source: Field Test Jan. 2010, n = 68

4.2 The rheology of the cement is optimized for the delivery system and also for clinical handling



9.4%	
6.3% 0.0%	84.4%

Fig. 2: Evaluation of the consistency of the cement when applying into or onto the restoration. Source: Field Test Jan. 2010, n=68

Fig. 3: Evaluation of the consistency of the cement when placing the restoration in the mouth.

4.3 Excess removal

Excess cement is best removed after brief – approximately two seconds – light exposure or alternatively during self-curing in the gel/wax-like state. Excess material of larger volume is easier to remove. The simplicity and easy excess removal is confirmed by 84% of dentists in a field test.

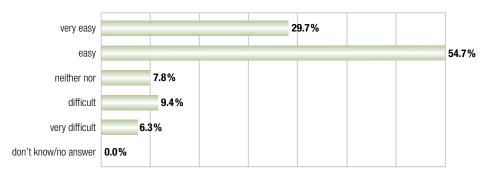




Fig. 4: Rating for excess removal. Source: Field Test Jan. 2010, n = 68

4.4 The perfect system: RelyX Unicem 2 Automix Cement and RelyX[™] Fiber Post

The endo tips facilitate easy access to the root canal, so you can apply cement in the canal from bottom to top. Compared to the traditional method of coating the post with cement before insertion, the risk of entrapping air bubbles and voids is much lower. This leads to outstandingly strong and virtually void-free post cementations.

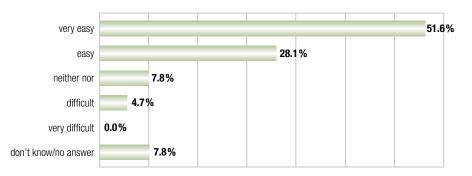




Fig. 5: Rating for usage of endo tips for post cementation. Source: Field Test Jan. 2010, n = 68

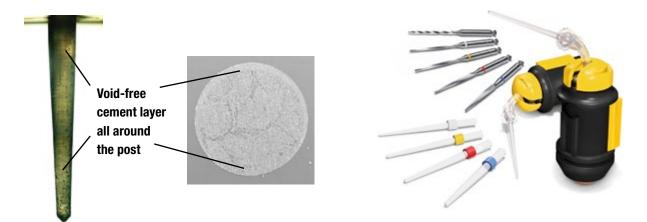


Fig. 6: The method of cement application determines the number of voids. Light microscopy and SEM images (cross section) of a simulated root canal filling in an acrylic glass test device. Source: Watzke R., Frankenberger R., Naumann M.; Probability of interface imperfections within SEM cross-sections of adhesively luted GFP. DentMater. 2009 Oct; 25(10): 1256-63

Material Properties

In summary, strong performance needs to be balanced over many clinical relevant criteria to help the restoration to become a clinical success. Those criteria go well beyond bond strength to tooth or to restorative material and include longevity, esthetics and marginal quality.

When several self-adhesive resin cements were compared, RelyX[™] Unicem 2 Automix Self-Adhesive Resin Cement showed very good values for all important parameters.

The strength of RelyX Unicem 2 Automix cement is the lack of a weakness — and that makes it reliable and successful.



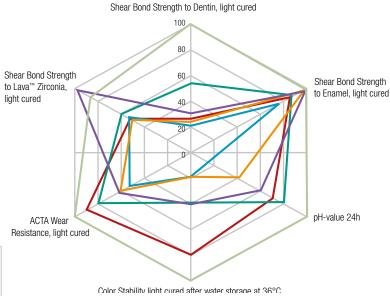


Fig. 7: Several self-adhesive resin cements were compared in different material properties. The best result achieved in each test was set to 100, the results of the other materials in the same test series were calculated in percent relative to the best. Source: 3M ESPE internal data

5.1 Bond strength

In independent research, RelyX Unicem 2 Automix cement shows the highest bond strength to dentin (Fig. 8), etchable ceramics and zirconia (Fig. 10), when compared to other self-adhesive resin cements.

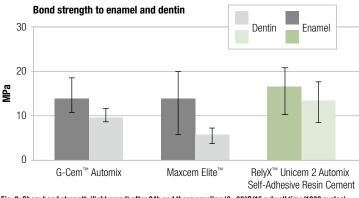


Fig. 8: Shear bond strength (light cured) after 24h and thermocycling (6–60°C/15 s dwell time/1000 cycles). Source: S Singhal, J Burgess, D Cakir et al. Birmingham, AL, USA. IADR 2010 # 139456

In this clinical relevant test design, Lava[™] Zirconia crowns are cemented onto slightly conical (10°) tooth preparations and pulled off. RelyX Unicem 2 Automix cement shows excellent retentive strength compared to other cements.

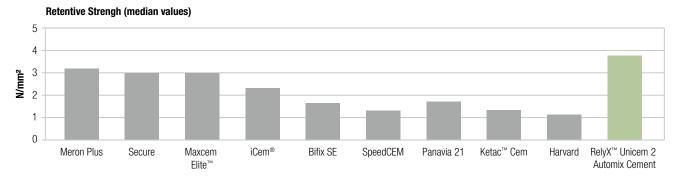
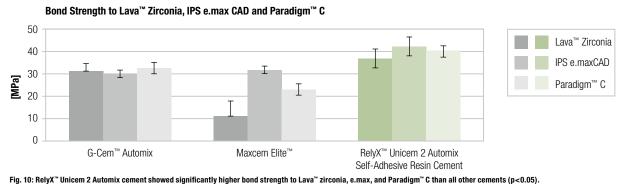


Fig. 9: Retention of zirconia crowns. Source: CP Ernst et al. Mainz, Germany. IADR 2010 # 394



Source: S Singhal, J Burgess, D Cakir et al. Birmingham, AL, USA. IADR 2010 # 395

RelyX Unicem 2 Automix cement performs at a high level on all substrates. The interface to tooth structure as well as to restoration materials is reliably bonded.

5.2 With RelyX Unicem 2 Automix cement, the retention rate for RelyX Fiber Posts is significantly greater than with other self-adhesive resin cements

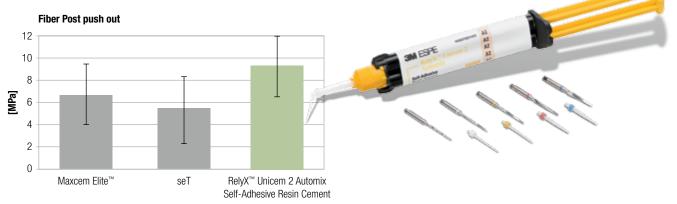
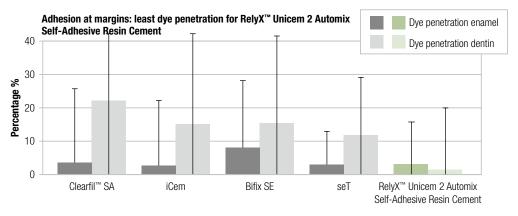


Fig. 11: RelyX[™] Unicem 2 Automix cement exhibited a significantly greater retentive ability and provided a better marginal seal in the root canal than the other self-adhesive resin cements. Source: Interfacial strength and morphology of new self-adhesive resin cements. A. CANTORO, C. GORACCI, A. MAZZONI, L. BRESCHI, and M. FERRARI ; IADR 2010 #621

5.3 Marginal sealing

Reliable marginal sealing is crucial for a long lasting restoration. Debonding to tooth structure would enhance the risk of secondary caries. RelyX Unicem 2 Automix cement shows impressive marginal sealing after artificial aging resulting in lowest dye penetration. SEM analysis confirms the dye penetration results. The integrity of bonding surfaces to tooth structure as well as to the restoration is obvious.



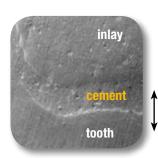


Fig. 13: Outstanding marginal sealing of RelyX[™] Unicem 2 Automix cement. Source: M. Rosentritt, C. Aschenbrenner, M. Behr et al. Regensburg, Germany. IADR 2010 #3976

Fig. 12: Dye penetration for MOD inlays after similation of 5 years clinical wear (Ic, thermocycling and mastication 1.2×106×50N, 6000×5°/55°C, 1.6HZ). Source: M. Rosentritt, C Aschenbrenner, M. Behr et al. Regensburg, Germany. IADR 2010 # 3976

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5.4 Abrasion resistance

Due to the optimal balance of mechanical properties, the wear resistance of RelyX[™] Unicem 2 Automix Self-Adhesive Resin Cement is superior. This helps maintain integrity over the lifetime of the restoration and prevents marginal discoloration due to marginal gaps.

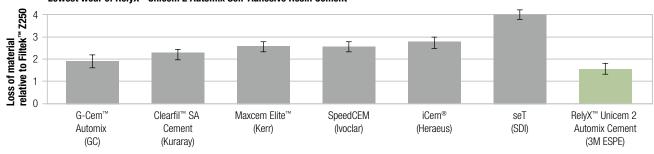




Fig. 14: ACTA-Abrasion test. Cements light cured. Source: 3M ESPE internal data

5.5 Consistency

The mixing quality is very important for final material performance. To achieve the best mixing results in a static mixing tip, the catalyst and base pastes need to flow into each other readily. Both pastes are well adapted in their rheology. The similar rheology leads to a homogeneously mixed material which can perform reliably in the clinical application.

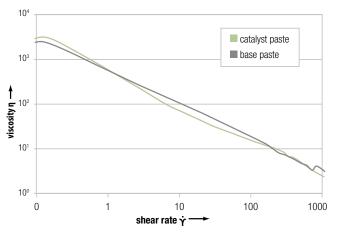


Fig. 15: The catalyst and the base paste show similar behaviour in viscosity when shearing. Source: 3M ESPE internal data

5.6 Long term stability (pH progression)

The pH-value increases during the setting of RelyX Unicem 2 Automix cement. Immediately after mixing RelyX Unicem 2 Automix cement, the cement paste is very acidic. Within a few minutes the pH-value starts to increase and within 24 hours it reaches a neutral level. After application to the tooth, the low pH-value of RelyX Unicem 2 Automix cement is crucial for the self-adhesive mechanism, whereas the pH increase is an essential prerequisite for the long-term stability of the cement.

Fig. 17: pH-values were measured using a pH indicator paper at different times after mixing the cement. Source: 3M ESPE internal data

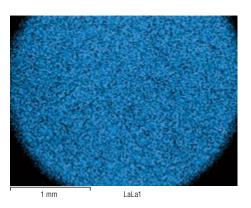
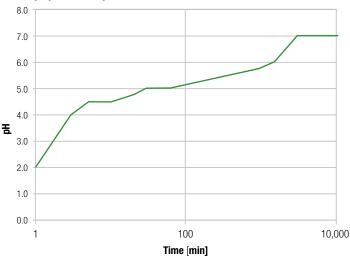


Fig. 16: Element (lanthanum) mapping of a RelyX[™] Unicem 2 sample shows homogeneous distribution over the cement disc surface. Source: 3M ESPE internal data



pH profile of RelyX[™] Unicem 2 Automix Self-Adhesive Resin Cement

The unique chemical formulation of RelyX[™] Unicem 2 Automix cement raises its pH to a neutral level after application. This contributes to the material becoming hydrophobic, meaning it is better able to resist water uptake, staining and cracking



Fig. 18: Results of stress test on self-adhesive resin cements. All samples were self-cured and thermocycled 10,000 times. Source: 3M ESPE internal data

5.7 Esthetics – Color stability

Compared to other leading products, RelyX Unicem 2 Automix cement clearly shows the lowest discoloration after incubation in a coffee solution. The pictures show cement samples after storage in standardized coffee solution for 3 days at 36 °C.



	before	after
RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement		
Maxcem Elite™		
SmartCem [®] 2		
G-Cem™		

Fig. 19: Storage of cement specimen (light cured) in standardized coffee solution for 3 days. Source: 3M ESPE internal data

5.8 Mechanical Properties overview

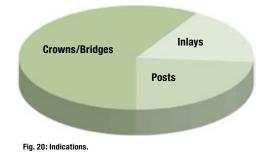
Properties	RelyX [™] Unicem 2 Automix Cement (Ic)	
Flexural strength [MPa]	99	
Compressive strength [MPa]	291	
Modulus of elasticity [GPa]	6.6	the weat the
Surface hardness [MPa]	190	and Existing and the
Film thickness [µm]	13	and the second se
Water sorption [µg/mm ₃]	28	
Solubility [µg/mm ₃]	0	
Expansion after 1 month [%]	0.63	
Source: 3M ESPE internal data		

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6 Clinical Performance

6.1 Results from field test

1,593 restorations were cemented by 68 dentists within the European application test. RelyX Unicem 2 Automix Self-Adhesive Resin Cement was used for the indications displayed in Fig. 20.



Overall satisfaction

97% of respondents were very satisfied or satisfied with RelyX Unicem 2 Automix cement.

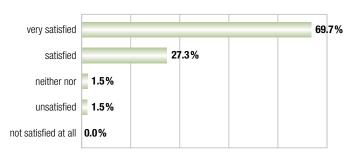
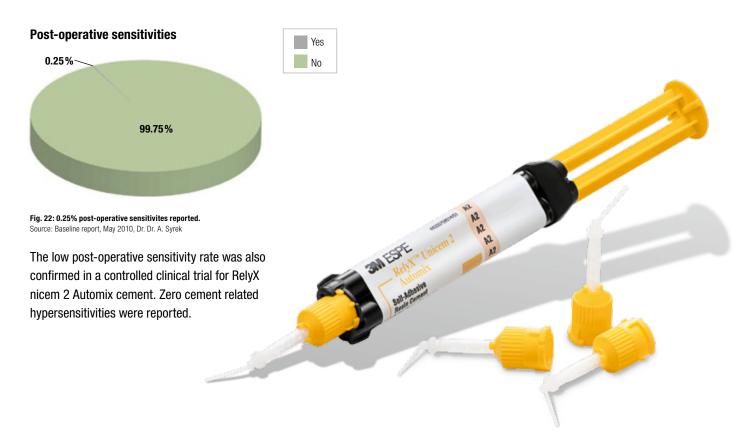


Fig. 21: Overall satisfaction with RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement. Source: Field Test Jan. 2010, n = 68

Post-operative sensitivities

Only 0.25% (4) sensitivities were reported for the 1593 restorations placed with RelyX Unicem 2 Automix cement (Fig. 22). Source: Field Test Jan. 2010, n = 68



6.2 Clinical cases

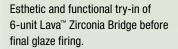
Restoration of the Anterior Region with a 6-unit Lava[™] Zirconia Bridge

Dr. med. dent. Jakob Zafran, Zurich, Switzerland

Initial situation.



Prepared abutment teeth and recovering gingiva after covering of the pontic area with a connective tissue graft.



Filling of the bridge abutments with RelyX[™] Unicem 2 Automix Self-Adhesive Resin Cement out of the automix syringe.

Restoration seated in the patient's mouth. Excess cement will be removed in the gel phase after initial curing.

Final light curing of RelyX[™] Unicem 2 Automix cement.

6-unit Lava zirconia bridge in situ after light curing and removal of excess cement. Also note improved pink esthetics.













All Ceramic Restoration on Root Treated Second Upper Premolar

Dr. Barbara Cerny, Munich, Germany

Initial situation.

Preparation of the root canal using RelyX[™] Fiber Post drills (3M ESPE).

Fit check of the RelyX[™] Fiber post (3M ESPE).

Extra-oral trimming of the RelyX Fiber post.

Attaching mixing tip with endo tip on RelyX Unicem 2 Automix syringe (3M ESPE).

Application of RelyX Unicem 2 Automix cement directly into the

























root cavity.

Insertion of the RelyX Fiber post.

Light curing using Elipar[™] S10 Curing Light from 3M ESPE.

Preparation for Lava[™] Crown.

Lava crown after final cementation.



Dental Products

3M Center Building 275-2SE-03 St. Paul, MN 55144-1000 U.S.A. 1-800-634-2249

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