Ketac™ Cem Plus

Resin Modified Glass Ionomer Cement

Technical Data Sheet

3M ESPE

1 Intro

Ketac™ Cem Plus Resin Modified Glass Ionomer Cement from 3M ESPE is a radiopaque, fluoride-releasing, resin modified glass ionomer luting cement. It is self-curing with the option of tack light-curing of excess cement. The cement is available in two delivery systems: Clicker™ Dispenser and automix syringe.

Ketac Cem Plus cement is ideal for the permanent cementation of porcelain-fused-to-metal (PFM) restorations as well as pediatric stainless steel crowns. It is also well suited for the cementation of crowns and bridges to implant abutments. This newest generation of the cement has a faster and easier delivery as well as tack-cure clean-up of excess cement. Reliable bond strength, fluoride release and an anti-inflammatory effect are further arguments to use this product.

Features and benefits at a glance:

- Tack light-cure feature for “clean-up on demand”
- Easy-to-use automix syringe allows for direct delivery into the crown (no hand-mixing)
- High bond strength to tooth structure and metal; no pre-treatment or conditioners required
- Anti-inflammatory effects
- Sustained fluoride release
- Virtually no post-operative sensitivity
- Long clinical history

Fig. 1: Tack-curing of Ketac™ Cem Plus Cement to remove excess easily.

Indications:

Ketac Cem Plus cement is ideally suited for the permanent cementation of:

- Porcelain-fused-to-metal (PFM) crowns and bridges
- Metal crowns, inlays and onlays
- Crowns made with all-alumina or all-zirconia cores such as 3M™ ESPE™ Lava™ or Procera AllCeram
- Prefabricated or cast endodontic posts
- Orthodontic bands and appliances
- PFM, metal, all-alumina or all-zirconia core restorations on implant abutments

Fig. 2: Ketac™ Cem Plus Cement is recommended for the cementation of restorations to implant abutments.

2 Material technology

Ketac™ Cem Plus Cement is a resin modified glass ionomer cement composed of two separate pastes dispensed from either an easy-to-use automix syringe or the Clicker™ Dispenser.

After mixing, two setting reactions occur: an acid-base reaction between the glass and the polycarboxylic acid and a free radical polymerization of the methacrylate polymer and HEMA (2-hydroxyethylmethacrylate).

Chemical composition of Ketac Cem Plus cement:

Paste A	Paste B
Radiopaque fluoroaluminosilicate glass (FAS glass)	Nonreactive zirconia silica filler
Opacifying agent	Methacrylated polycarboxylic acid
2-Hydroxyethylmethacrylate	2-Hydroxyethylmethacrylate
Water	Resin monomers
Dispersion aid	Water
Reducing agent that allows for the self-cure methacrylate setting	Potassium persulphate
	Photoinitiator

A unique component of the formula for Ketac Cem Plus cement is the photoinitiator that enables optional tack light-curing of the excess cement.

Instead of waiting 2 to 3 minutes for the self-cure gel phase before excess cement can be cleaned, there is now an option to light-cure the excess cement for 5 seconds per surface and begin cleaning immediately. An instant resin network is built, which reduces moisture sensitivity during setting.

Fig. 3: Excess cement.

Fig. 4: Light-cure of excess cement for 5 seconds per surface.

Fig. 5: Easy removal of excess in one piece.

In addition to the typical features of a glass ionomer cement, such as fluoride release, Ketac Cem Plus cement also contains a resin component, which gives it a unique combination of physical and mechanical properties.

3 Bond strength performance

Ketac™ Cem Plus Cement is based on the resin modified glass ionomer technology that combines the favourable features of conventional glass ionomer, such as fluoride release, with those of resin-based cements, such as reliable bond strength.

3.1 Bond strength to enamel and dentine

Ketac Cem Plus cement has an inherent ability to create a molecular bond to tooth structure. Although some glass-ionomer-based products need an additional conditioner on the tooth surface to promote adhesion, Ketac Cem Plus cement does not need a separate conditioning step.

Fig. 6 shows Ketac Cem Plus cement's significantly superior shear bond strength to enamel and dentine without conditioner in comparison to other glass-ionomer- or zinc-phosphate-based cements.

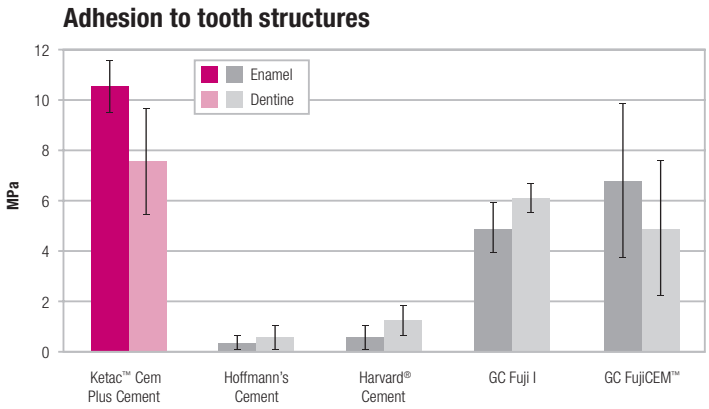


Fig. 6: Shear bond strength to tooth structure, cements used without conditioner. Source: Y. Wang, T. Ton, A. Falsafi, J.D. Oxman, E. Popp, and T. Tran: Adhesion of Glass-Ionomer and Zinc Phosphate Cements to Different Substrates, J Dent Res 92 (Spec Iss A): 2379, 2013 (www.dentalresearch.org).

3.2 Bond strength to metal

Ketac Cem Plus cement is well suited for the cementation of metal-based restorations. According to Wang et al., it has a significantly higher shear bond strength to metal than other glass-ionomer- and zinc phosphate-based cements (Fig. 7).

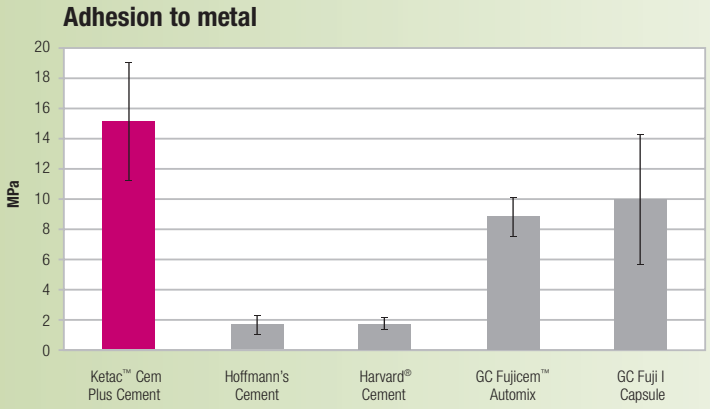


Fig. 7: Shear bond strength to metal. Source: Y. Wang, T. Ton, A. Falsafi, J.D. Oxman, E. Popp, and T. Tran: Adhesion of Glass-Ionomer and Zinc Phosphate Cements to Different Substrates, J Dent Res 92 (Spec Iss A): 2379, 2013 (www.dentalresearch.org).

4 Marginal integrity

It is well known that water-based cements generally suffer from solubility and erosion in the early stage of setting (1 hour to 1 day) before the cement has reasonably matured[1,2]. Incorporation of resin components into such cements, resulting in a resin modified glass ionomer cement, allows for the formation of a resin-based network[1,3]. This network can be formed in dark-cure and/or light-cure modes, providing maximum protection of the cement from early dissolution and erosion without any need for extra coatings or sealants.[1,2]

The photoinitiator in the new formula for Ketac™ Cem Plus Cement enables instant network formation after 5 seconds of tack-curing per surface, resulting in reduced moisture sensitivity and immediate excess cement removal.

A clinical evaluation by 135 dentists evaluated excess cement clean-up after 5 seconds' tack-curing per surface and after 2 minutes' waiting time. The dentists rated performance criteria for excess cement removal and speed of clean-up. Their ratings are shown in Fig. 8.

Tack light-cure makes clean-up faster and easier

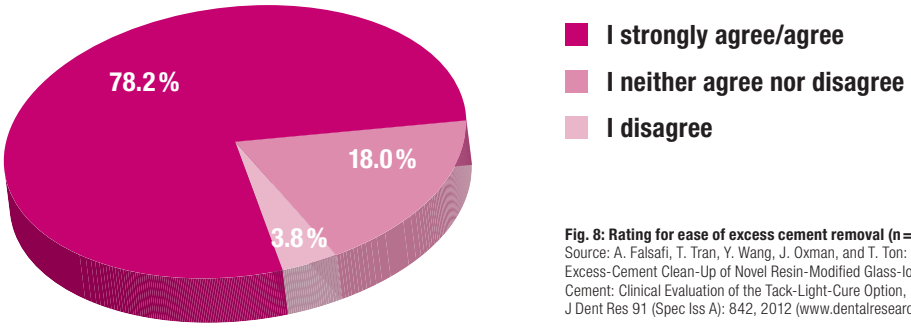


Fig. 8: Rating for ease of excess cement removal (n = 135).
Source: A. Falsafi, T. Tran, Y. Wang, J. Oxman, and T. Ton: Excess-Cement Clean-Up of Novel Resin-Modified Glass-Ionomer Cement: Clinical Evaluation of the Tack-Light-Cure Option, J Dent Res 91 (Spec Iss A): 842, 2012 (www.dentalresearch.org).

4.1 Marginal sealing

First and foremost, marginal sealing determines the long-term success of a cemented restoration. The efficient marginal seal to enamel and dentine of Ketac Cem Plus cement after tack-curing was confirmed in an in vitro study at the University of Regensburg, Germany. Ketac Cem Plus cement revealed 100% perfect margins to dentine before and after thermocycling and mechanical loading (TCML) when the tack-cure feature was used for excess removal.[3]

The marginal integrity of Ketac Cem Plus cement to dentine and enamel before and after TCML was closer to perfect than for any other resin modified glass ionomer cement.[4]

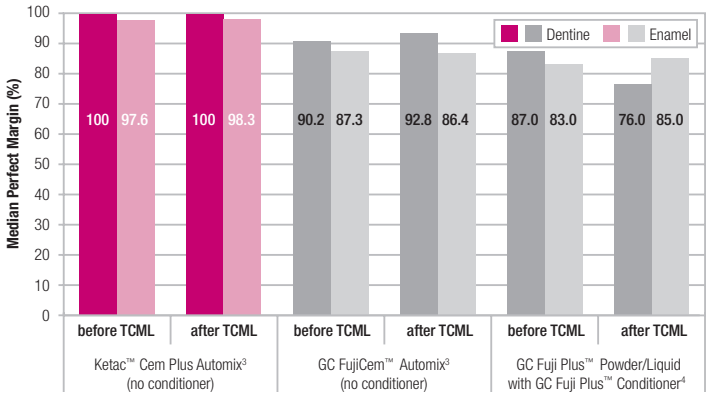


Fig. 9: Schematic representation of the study results. Sources: A. Sawaljanow, R. Lang, G. Handel, M. Behr, and M. Rosentritt. *In-Vitro* Marginal Adaptation of Resin-Modified Glass Ionomer Cements to Dentin and Enamel. J Dent Res 92 (Spec Iss A): 2345, 2013 (www.dentalresearch.org); adapted from M. Rosentritt, M. Behr, R. Lang, and G. Handel. Influence of Cement Type on the Marginal Adaptation of All-Ceramic MOD Inlays. Dent Mater. 2004 Jun; 20 (5):463-469.

[1] Glass-Ionomer Cement, Wilson, A.D. and McLean, J.W.; Quintessence Books, 1988, pp. 51-52
[2] An Atlas of Glass-Ionomer Cements, Mount, G.J.; Dunitz, 2002, pp. 5-7.
[3] Sawaljanow, A., Lang, R., Handel, G., Behr, M., and Rosentritt, M. In-Vitro Marginal Adaptation of Resin-Modified Glass Ionomer Cements to Dentin and Enamel, I. J Dent Res 92 (Spec Iss A): 2345, 2013 (www.dentalresearch.org).
[4] Adapted from Rosentritt, M., Behr, M., Lang, R., and Handel, G. Influence of Cement Type on the Marginal Adaptation of All-Ceramic MOD Inlays. Dent Mater. 2004 Jun; 20 (5):463-469.

4.2 Fluoride release

Ketac™ Cem Plus Cement provides sustained fluoride release, which is a key feature of glass-ionomer-based cements. It is generally believed that the release of fluoride ions and their uptake into the tooth structure aid in the reduction of secondary caries[5], which can be difficult to detect under a crown or bridge.

Cumulative fluoride release for Ketac Cem Plus cement was measured by Ogami et al., as shown in Fig. 10. Fluoride release from cured discs (8 × 2 mm) of two products, Ketac Cem Plus cement and GC Fujicem 2, was measured for 14 days using an Ion Analyser (Model 290, Orion Research) with Ion Electrode (Model 9609, Orion Research) and TISAB (Total Ion Strength Adjustment Buffer) solution.

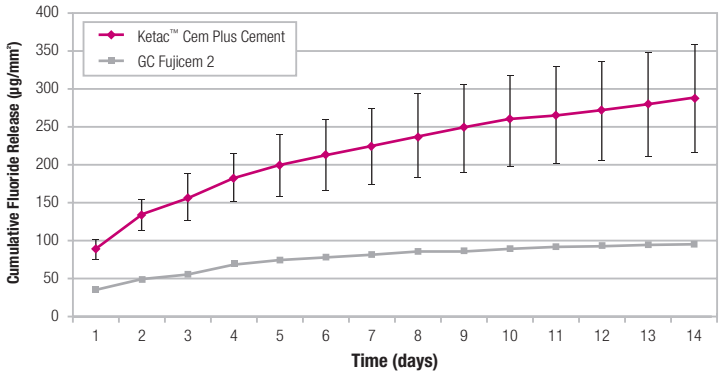


Fig. 10: Difference in the amount of fluoride release in fluoride-releasing cements. Source: K. Ogami, T. Koike, T. Ueda, and K. Sakurai, Department of Removable Prosthodontics and Gerodontology, Tokyo Dental College.

4.3 Anti-inflammatory effect

Gingivitis is an inflammatory multi-factorial process affecting the mucosal epithelial tissue. Plaque mass and plaque activity are considered to contribute to the incidence of gingivitis.[6]

A study by Syrek et al.[7] investigated plaque growth and plaque activity inhibition in a Plaque Glycolysis and Regrowth Model (PGRM). The study shows that, in comparison to bovine enamel and dentine, Ketac Cem Plus cement inhibits plaque accumulation and plaque activity. Both indicate that the bioactivity of Ketac Cem Plus cement might contribute to preventing inflammatory processes of soft tissue such as gingivitis or peri-implantitis.

In this study, human saliva was used to grow plaque on bovine enamel, dentine and samples of Ketac Cem Plus cement. Plaque growth was initiated with a 1:4 mixture of human saliva and MCM-sucrose-culture media. Plaque was collected and dried to determine its biomass and related to the exposed surface area of each specimen. In accordance with the PGRM, lactic acid release was quantified by using the Clinpro™ Cario L-Pop™ from 3M ESPE (Fig. 11).

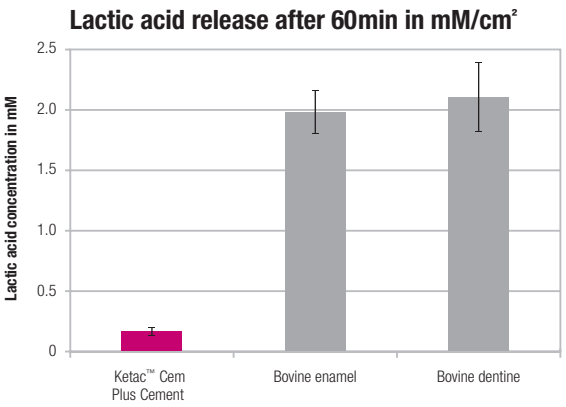


Fig. 11: Less plaque accumulation and growth activity on Ketac™ Cem Plus Cement. Source: A. Syrek, P.J. Flanigan, M. Hauke, and I. Häberlein. Bioactivity of a Luting-Cement to Support Prevention of Soft-Tissue Inflammation. J Dent Res 92 (Spec Iss A): 184, 2013. (www.dentalresearch.org).

[5] Hicks, M.J., and Flaitz, C.M., Quintessence Int. 2000 Sep; 31(8): 570-578.
[6] FDA Guidance for Industry: Gingivitis (2005), monograph (21 CFR Part 356) Testing of the antigingivitis/ antiplaque effectiveness of drug products.
[7] Syrek, A., Flanigan, P.J., Hauke, M., and Häberlein, I. Bioactivity of a luting-cement to support prevention of soft-tissue inflammation. J Dent Res 92 (Spec Iss A): 184, 2013. (www.dentalresearch.org).

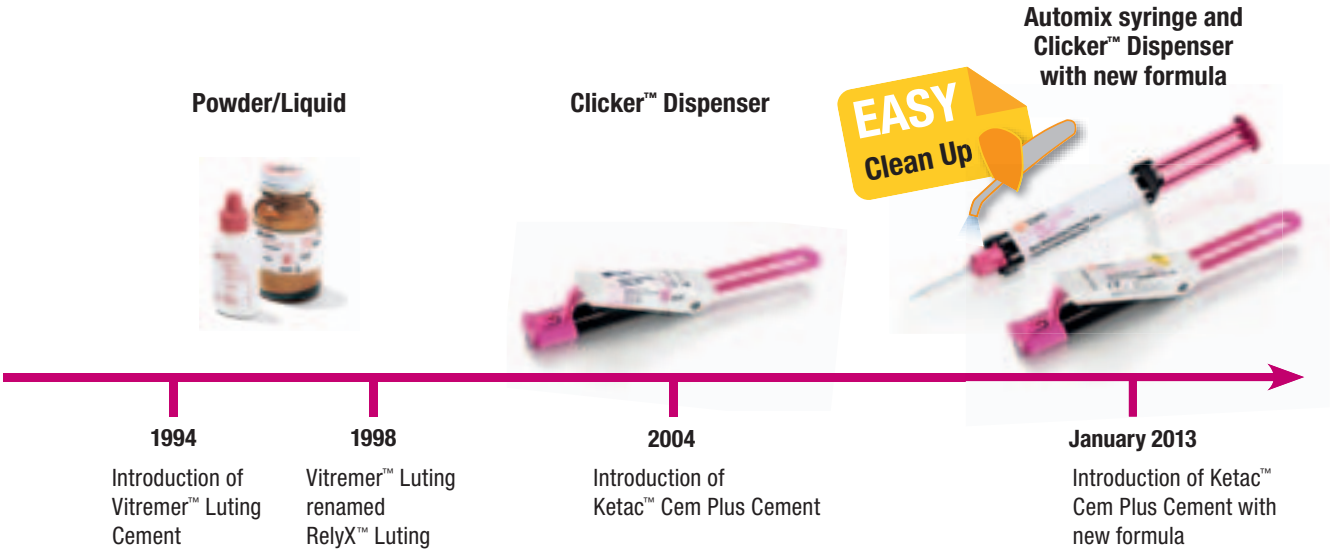
4.4 Overview of physical and mechanical properties

The physical properties of Ketac™ Cem Plus Cement passed all ISO 9917-2:2010 tests for a class 1, water-based, resin modified luting cement.

Physical properties	Unit	Value
Compressive strength	MPa	135 ± 5.2
Diametral tensile strength	MPa	22.3 ± 1.2
Flexural strength	MPa	34.0 ± 3.0
Shear bond strength to dentine	MPa	7.6 ± 2.1
Shear bond strength to enamel	MPa	10.6 ± 1.0
Shear bond strength to metal	MPa	15.1 ± 3.9
Shear bond strength to zirconia	MPa	5.7 ± 3.4
Shear bond strength to titanium	MPa	8.5 ± 1.8
Film thickness	µm	19.0 ± 3.16
Radiopacity	mm	1.41 ± 0.1
Particle size	µm	3

5 Clinical performance

3M has a long and successful history with resin modified glass ionomer cements (RMGIs). RelyX™ Luting (formerly known as Vitremer™ Luting, introduced in 1994), Ketac™ Cem Plus Clicker™ (introduced in 2004), and now, Ketac™ Cem Plus Cement (available in the Clicker™ Dispenser and automix syringe) with a new material formula are all products of 3M ESPE resin modified glass ionomer cement technology. All three share the same overall chemistry and performance, as has been documented in numerous studies. Their clinical success and proven performance have been documented and cited over 18 years of use in dental practice.



In a published survey of U.S. Dental Schools on cementation protocols for implant crown restorations[8], most institutions reported the use of permanent cements for implant crown restorations. The most often used cement was a resin modified glass ionomer cement. These findings are supported by results of a field evaluation for Ketac Cem Plus cement conducted by AFG Research in 2012. Dentists' preferred choice for the cementation of restorations to implant abutments is a resin modified glass ionomer cement like Ketac Cem Plus cement.

[8] Tarica, D.Y., DDS, Alvarado, V.M., DDS, and Truong, S.T., DDS. Survey of United States Dental Schools on Cementation Protocols for Implant Crown Restorations, Veterans Administration Greater Los Angeles (VAGLA) Healthcare System, Los Angeles, California.

5.1 Field evaluation

The 2012 field evaluation survey aimed to assess dentists' satisfaction. Participants were asked multiple questions to measure their attitude towards Ketac™ Cem Plus Cement and give their feedback on various product features.

The research was conducted by AFG Research via a web-based survey as a follow-up on the product evaluation/trial period of four weeks. More than 110 dentists from Germany and the U.S. were pre-selected to try Ketac Cem Plus cement in the Clicker™ Dispenser. The dentists' feedback confirms their very high overall satisfaction: **More than 76% would very likely or likely recommend Ketac Cem Plus cement to their colleagues (Fig. 12).**

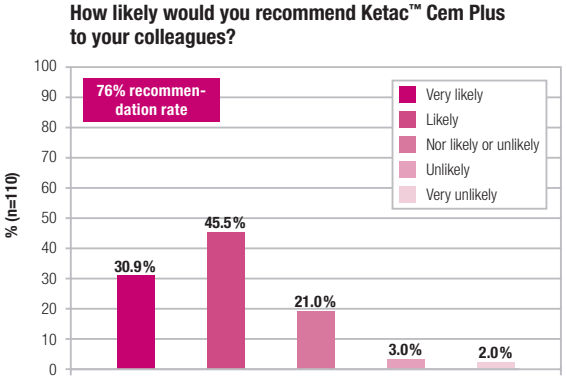


Fig. 12: Recommendation rate after testing Ketac™ Cem Plus Cement.
Source: Field Evaluation 2012 conducted by AFG Research on behalf of 3M ESPE.

5.2 For each indication – the ideal cement

3M ESPE offers a wide spectrum of cements. Ketac Cem Plus cement is a perfect addition to the 3M ESPE cement portfolio and is ideally suited for metal/metal based restorations and the cementation of restorations to implant abutments.

	RelyX™ Ultimate Adhesive Resin Cement	**RelyX™ Unicem** **RelyX™ Unicem 2** Self-Adhesive Resin Cement	**Ketac™ Cem Plus** Resin Modified Glass Ionomer Cement	**RelyX™ Veneer** Veneer Cement
Metal / Metal based				
Inlays / Onlays	+	++	+	-
Crowns / Bridges	+	++	++	-
Endodontic Posts	+	++	++	-
Maryland Bridges	++	+	-	-
on Implant Abutments	+	++	++	-
Glass Ceramics (incl. Li. Disilicate) (e.g. e.maxCAD, Empress, Vitamark II)				
Inlays / Onlays / Table Tops	++	+	-	-
Crowns / Bridges	++	++	-	-
Maryland Bridges	++	+	-	-
Veneers	+	-	-	++
Oxide Ceramics (e.g. Lava™ Zirconia Brux Zir)				
Crowns / Bridges	+	++	+	-
Endodontic Posts	+	++	+	-
Maryland Bridges	++	+	-	-
on Implant Abutments	+	++	++	-
Resin Nano Ceramics (e.g. Lava™ Ultimate CAD/CAM Restorative)				
Inlays / Onlays	++	-	-	-
Crowns	++	-	-	-
Veneers	+	-	-	++
Resin Composites				
Inlays / Onlays	++	+	-	-
Crowns	++	++	-	-
Endodontic Posts	+	++	-	-
Veneers	+	-	-	++

++ Highly recommended* + Recommended - Not indicated

*Either better performance for this indication or easier handling at equal performance.

Clinical case

Cementation of a PFM crown | Dr. G. Reich, Munich, Germany and Zahntechnische Werkstätten Borgmann und Zink, Weilheim, Germany

1

Initial situation: Largely extended insufficient amalgam filling on first molar needs to be replaced by a PFM crown.

2

Prepared tooth is cleaned with pumice to remove any remnants of temporary cement.

3

Prepared tooth is rinsed and dried prior to cementation. Tooth surface is left moist and not overdried.

4

Mixing tip is attached to the Ketac™ Cem Plus automix syringe.

5

A peppercorn-sized amount of material is discarded to make sure the material is properly mixed.

6

Ketac™ Cem Plus Cement is directly applied into the crown.

7

Crown is seated.

8

Excess cement is tack light-cured for 5 seconds on each surface.

9

Wax-like excess cement is removed easily in one large piece.

10

Final situation: PFM crown *in situ.*

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