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# Ketac™ Universal Aplicap™ Glass Ionomer Restorative

## Technical Product Profile



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# Introduction

**Ketac™ Universal Aplicap™ Glass Ionomer Restorative is the latest development in a long history of proven glass ionomer technology from 3M. It's designed to save steps for a faster procedure, so it's ideal for treating pediatric, geriatric and teenage patients, who can be the most caries-prone and the most restless. Ketac Universal Aplicap restorative offers low stickiness for easy handling AND reduces chair time with a simple one-step placement ... so you can finish faster. The material can be used without preconditioning the cavity and without a coating, so it eliminates steps, yet still delivers the compressive strength and surface hardness that are higher than several competitive glass ionomers which require a coating. Ketac Universal Aplicap restorative is mixed in triturated capsules to initiate the acid-base setting reaction of the glass ionomer. The capsule has a tapered nozzle, which enables better access to the cavity for the one-step procedure. The material is indicated for an extended range of indications, making it a universal solution for the dental practice.**

## Product Description

Ketac™ Universal Aplicap™ Glass Ionomer Restorative is a radiopaque glass ionomer restorative in capsules used for bulk fillings.

The ability of the material to chemically bond to enamel and dentin provides for minimally invasive preparation and excellent sealing of the margins of fillings. Ketac Universal Aplicap restorative can be applied without lining or glaze/coating. It releases fluoride ions and is available in various shades corresponding to the VITA® classical shade guide. The minimum dispensable quantity of a capsule is 0.13 ml.

## Product Features

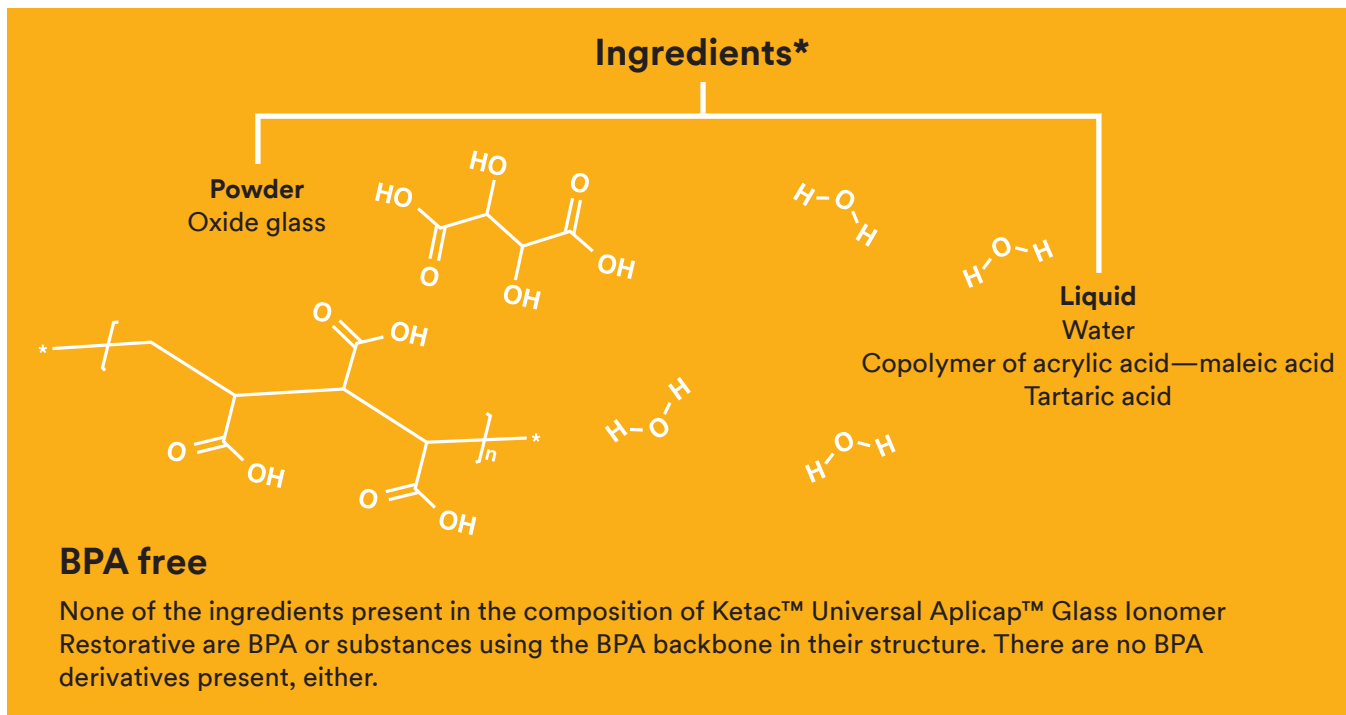
- Packaged in capsules with a powder and a liquid component
  - Capsules are transparent with turquoise clips
  - Minimum dispensable quantity of a capsule is 0.13 ml
- 6 shades—White, A1, A2, A3, A3.5 and A4
- Long-term Class I and Class II with restrictions\*
- No need for conditioner or coating
- Bulk fill—no need for layering
- Enables fast, one-step, stress-bearing restorative solutions
- Extended indications for use compared to other glass ionomer materials
- Continuously releases fluoride for 24 months
- Low stickiness for an easy placement
- Self-adhesive
- Self-cure
- Radiopaque

\*Refer to the Instructions for Use for more information

# Indications for Use

- Linings for single- and multiple-surface composite fillings
- Core build-up prior to crown placement
- Primary tooth fillings
- Stress-bearing Class I restorations with at least one additional support outside of the filling area
- Stress-bearing Class II restorations when the isthmus is less than half of the intercuspal distance and with at least one additional support outside of the filling area
- Cervical fillings, if aesthetics is not the prime consideration
- Single- and multiple-surface temporary fillings
- Fissure sealing

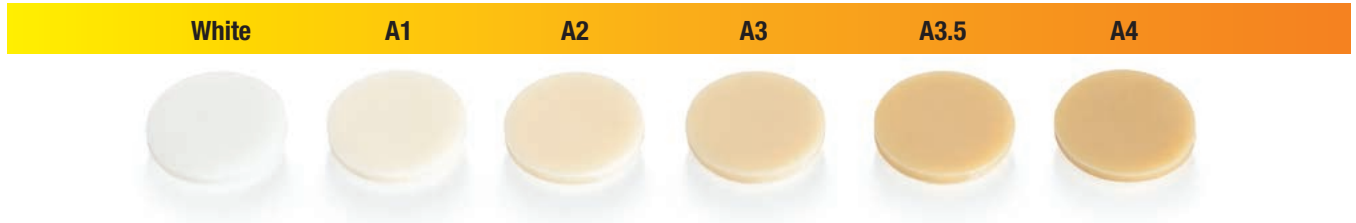
# Composition



\*Refer to MSDS for more information

## Shades

Ketac™ Universal Aplicap™ Glass Ionomer Restorative is available in 6 shades: White, A1, A2, A3, A3.5 and A4.



## Simplified Dental Treatment

Glass ionomer restoratives have a long history of being an economical, tooth-colored solution for treating caries. Currently, most traditional glass ionomer restoratives on the market require a conditioner and/or coating. Ketac Universal Aplicap restorative takes ease of use one step further by eliminating these steps.

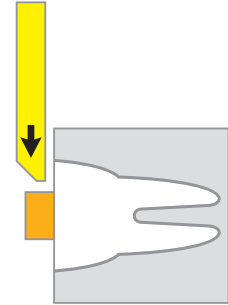
### Fewer steps = a simple, faster procedure

	Ketac™ Universal Aplicap™ Glass Ionomer Restorative	GC Fuji IX GP®	EQUIA™ Fil
<b>Steps after cavity preparation*</b>	<b>only 4 steps</b>	<b>13 steps</b>	<b>13 steps</b>
Cavity conditioner		●	●
Rinse		●	●
Air dry		●	●
Shake capsule		●	●
Activate capsule	●	●	●
Prime capsule		●	●
Mix capsule (Mixing device)	●	●	●
Place in bulk	●	●	●
Coating		●	●
Light cure/air dry		●	●
Finishing	●	●	●
Coating		●	●
Light cure/air dry		●	●

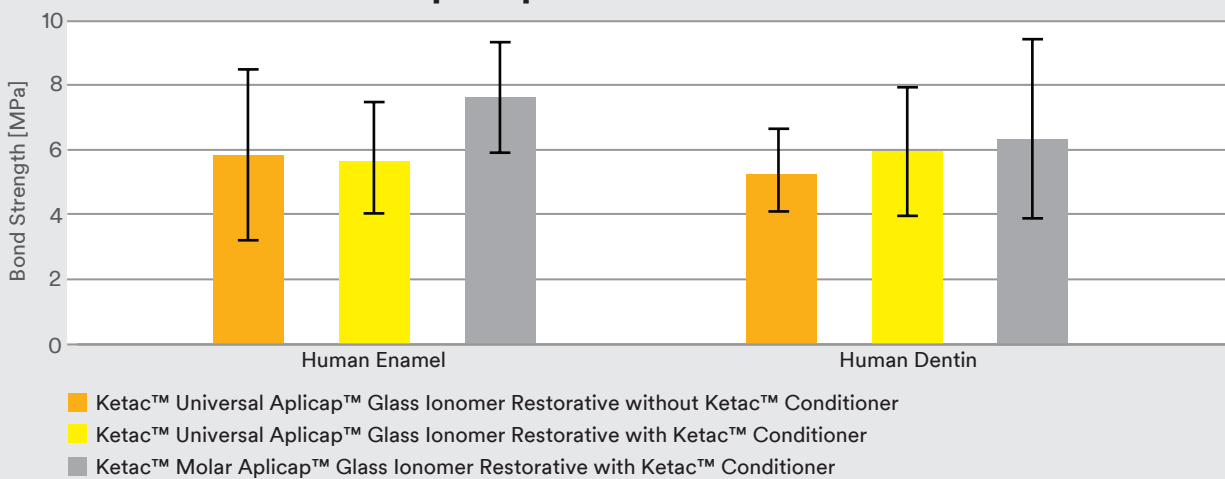
\*Clinical steps according to manufacturer's Instructions for Use

# Adhesion

To evaluate the influence of the conditioning step, adhesion was tested with and without a conditioner. Bond strength on human teeth was measured using a Shear Bond Test. The material was cured on exposed human enamel/dentin. Specimens were then kept at 36°C and over 95% relative humidity for 24 hours. Adhesion was subsequently tested in a universal testing machine cell until failure.



## Bond strength to enamel and dentin of Ketac™ Universal Aplicap™ Glass Ionomer Restorative



**Figure 1: Adhesion to enamel and dentin. The adhesion values of Ketac™ Universal Aplicap™ Glass Ionomer Restorative without a conditioner are comparable to the adhesion values of Ketac™ Universal Aplicap™ restorative and Ketac™ Molar Aplicap™ Glass Ionomer Restorative with a conditioner. Therefore, the application of a conditioner prior to placement of Ketac™ Universal Aplicap™ restorative is not necessary.**



**Ketac Universal Aplicap restorative offers comparable adhesion values whether used with or without a conditioner, so a conditioner is not necessary.**

The results are in line with multiple *in vivo* and *in vitro* studies, which have shown that using a conditioner does not necessarily improve the adhesion of glass ionomers to the natural tooth structure. Literature shows that application of a conditioner prior to placement of the filling is successful in removing the “smear” layer. However, this step is not necessary, possibly because there is adequate free acid in glass ionomers to dissolve the smear layer at the time of the restoration placement.\*

\*Yassen, G. (2009). One-year survival of occlusal ART restorations in primary molars placed with and without cavity conditioner. *Journal of Dentistry for Children*. 76:136-141.

van Dijken, J. W. V. (1996). Four-year evaluation of the effect of 10% polyacrylic acid or water rinsing pretreatment on retention of glass polyalkenoate cement. *European Journal of Oral Sciences*. 104:64-66.

Tyas, M. J. (1994). The effect of dentine conditioning with polyacrylic acid on the clinical performance of glass ionomer cement—3-year results. *Australian Dental Journal*. 39:220-221.

Bortoletto, C. C., Junior Miranda, W. G., Motta, L. J., Bussadori, S. K. (2013). Influence of acid etching on shear strength of different glass ionomer cements. *Brazilian Journal of Oral Sciences*. 12: 11-15.

# Physical Properties

## Mechanical Properties Overview

The mechanical properties of the medium-viscous Ketac™ Universal Aplicap™ Glass Ionomer Restorative are comparable to clinically effective high-viscous materials such as Ketac™ Molar Aplicap™ Glass Ionomer Restorative.

Properties	Ketac™ Universal Aplicap™ Glass Ionomer Restorative	Ketac™ Molar Aplicap™ Glass Ionomer Restorative
Compressive strength	251 ± 14 MPa	246 ± 18 MPa
Flexural strength	50 ± 4 MPa	52 ± 9 MPa
Surface hardness	667 ± 111 MPa	647 ± 34 MPa
Wear resistance 3-body wear	66 ± 5 µm	72 ± 10 µm

Source: 3M internal data

## Compressive Strength

Compressive strength is particularly important because of chewing forces. To test this, simultaneous forces were applied to the opposite ends of a rod-shaped sample of material. The sample failure is a result of shear and tensile forces.

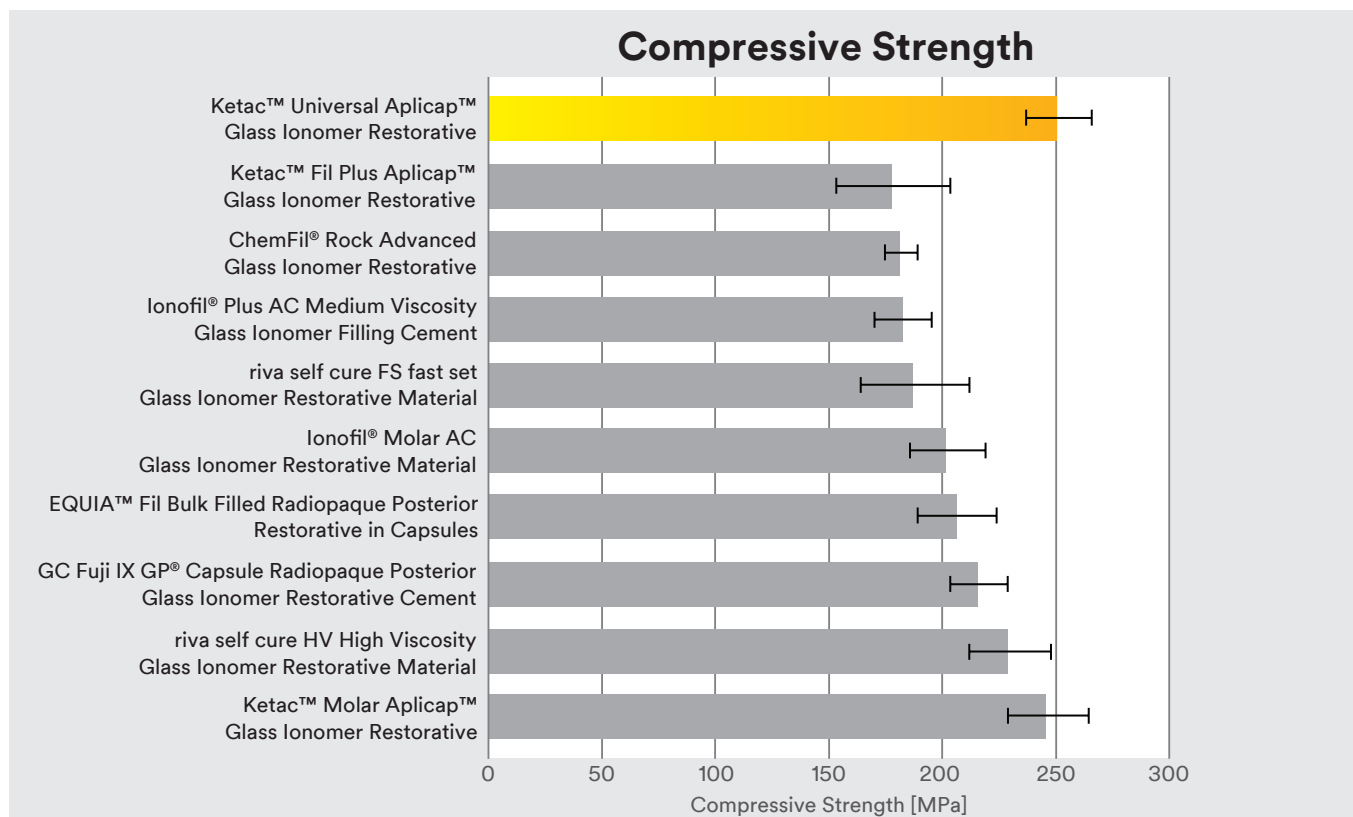


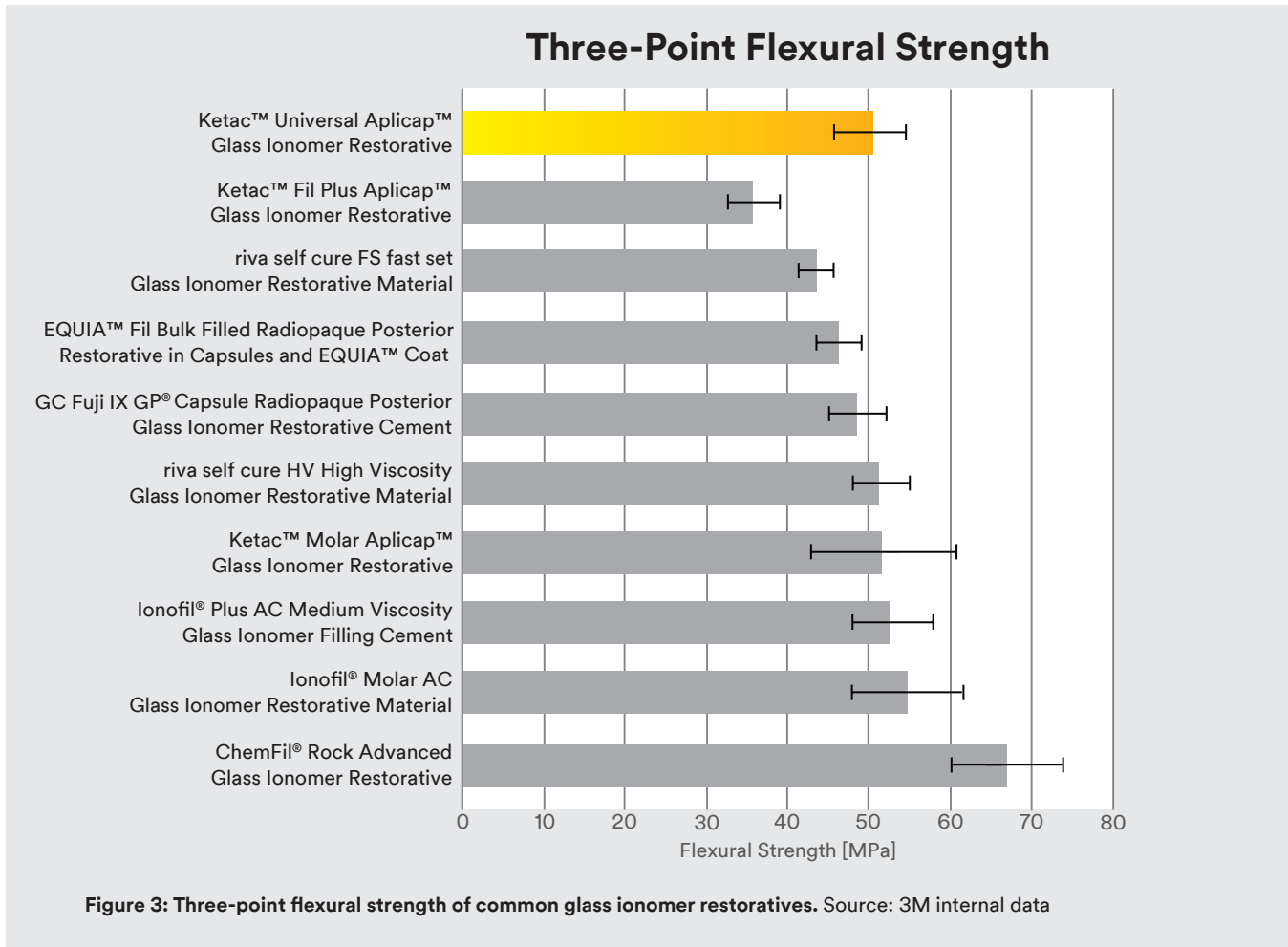
Figure 2: Compressive strength of common glass ionomer restoratives. Source: 3M internal data



The compressive strength of Ketac Universal Aplicap restorative is significantly higher than several competitive glass ionomer restoratives in capsules, including GC Fuji IX GP Capsule, EQUIA Fil, ChemFil Rock, Ionofil Plus AC, Ionofil Molar AC, riva self cure FS fast set and Ketac™ Fil Plus Aplicap™ Glass Ionomer Restorative.

## Flexural Strength

Flexural strength was measured by applying a perpendicular load to a material specimen that is supported at each end. Flexural strength is the value obtained when the sample breaks.



The flexural strength of Ketac™ Universal Aplicap™ Glass Ionomer Restorative is statistically equivalent to all competitive glass ionomer restoratives shown except for ChemFil Rock and Ketac™ Fil Plus Aplicap™ Glass Ionomer Restorative.



## Surface Hardness

Surface hardness was measured on disc-shaped specimens (diameter 6 mm) 24 hours after mixing the restorative. A testing machine with a ball-shaped indenter (diameter 5 mm) was used. Samples were loaded with a force of 357.9 N for 30 seconds. Thereafter, depth of penetration was measured and the surface hardness calculated.

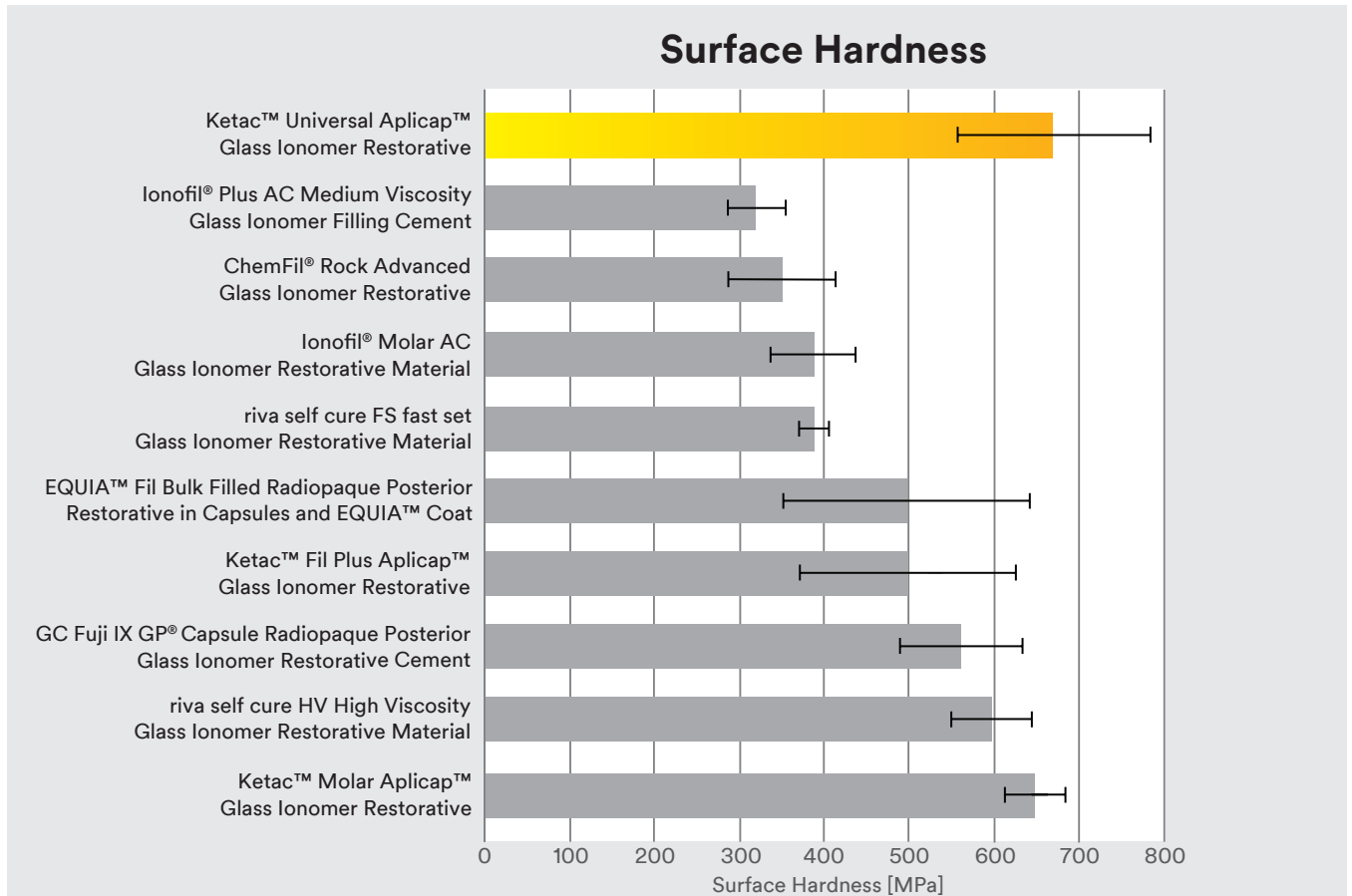


Figure 4: Surface hardness of common glass ionomer restoratives. Source: 3M internal data



The surface hardness of Ketac™ Universal Aplicap™ Glass Ionomer Restorative is higher than Ionofil Plus AC, ChemFil Rock, Ionofil Molar AC, riva self cure FS fast set, EQUIA Fil, Ketac™ Fil Plus Aplicap™ Glass Ionomer Restorative, and equivalent to GC Fuji IX GP Capsule, riva self cure HV and 3M's own Ketac™ Molar Aplicap™ Glass Ionomer Restorative.

## In vitro, 3-Body Wear

The wear rate was determined by an in vitro 3-body wear test. In this test, the restorative material (first body) is loaded onto a wheel, which contacts another wheel, that acts as an “antagonistic cusp” (second body). The two wheels counter-rotate against one another, dragging abrasive slurry (third body) between them. Wear is measured as dimensional loss during 200,000 cycles, which is determined by profilometry at the end.

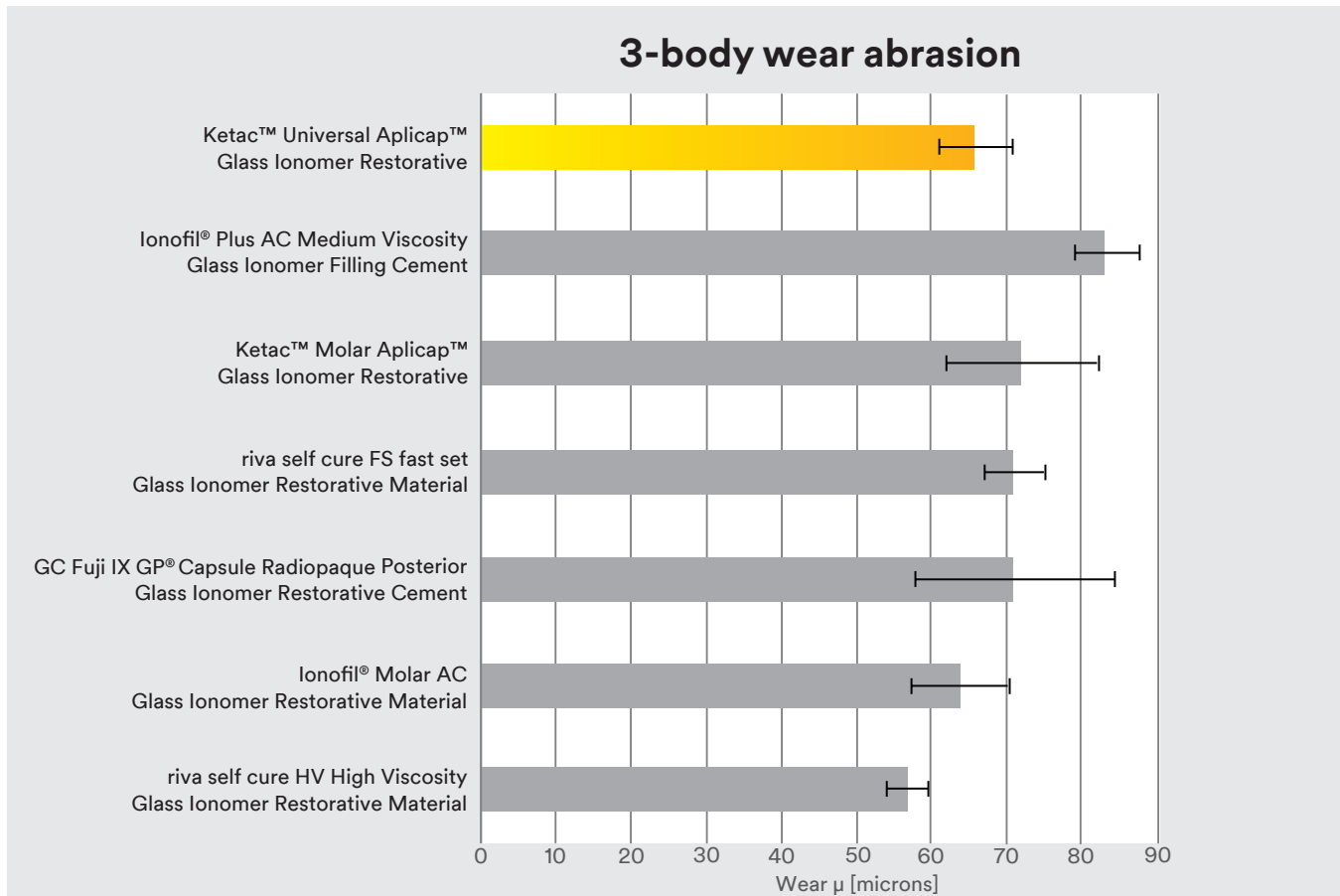
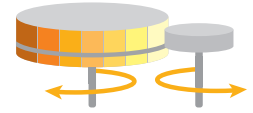


Figure 5: 3-body wear of common glass ionomer restoratives. Source: 3M internal data



The lower the wear, the better the wear resistance. Ketac™ Universal Aplicap™ Glass Ionomer Restorative wears less than Ionofil Plus AC and Ketac™ Molar Aplicap™ Glass Ionomer Restorative, and as much as GC Fuji IX GP Capsule, Ionofil Molar AC and riva self cure FS fast set Capsule.

## Stickiness

The quality of being non-sticky is a fundamental factor for the practitioner. While a restorative material should not stick to dental instruments while filling the cavity, it should be sticky enough to stay in the prepared cavity.

This laboratory test mechanically simulates a ball plunger being placed onto restorative material and removed, highlighting the level of “pull back” or stickiness of a material—as seen in the pictures below.



Figure 6: Test method: dipping of the plunger into the mixed paste and withdrawal immediately afterwards.



Figure 7: Stickiness test: different materials after withdrawal of the steel ball. Source: 3M internal data



While Ketac™ Universal Aplicap™ Glass Ionomer Restorative does not stick to the metal ball, other glass ionomer materials display a clear “pull back” effect when the ball plunger is lifted.

## Ease of Placement

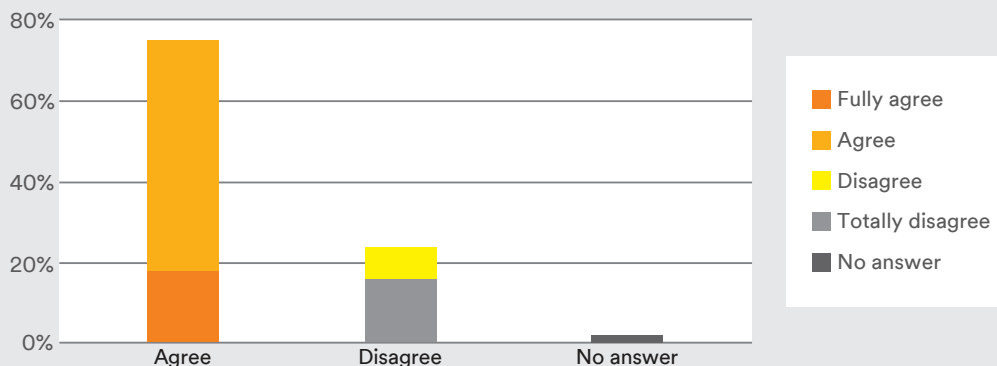


Figure 8: Low stickiness to instruments allows easy placement. Source: 3M internal data



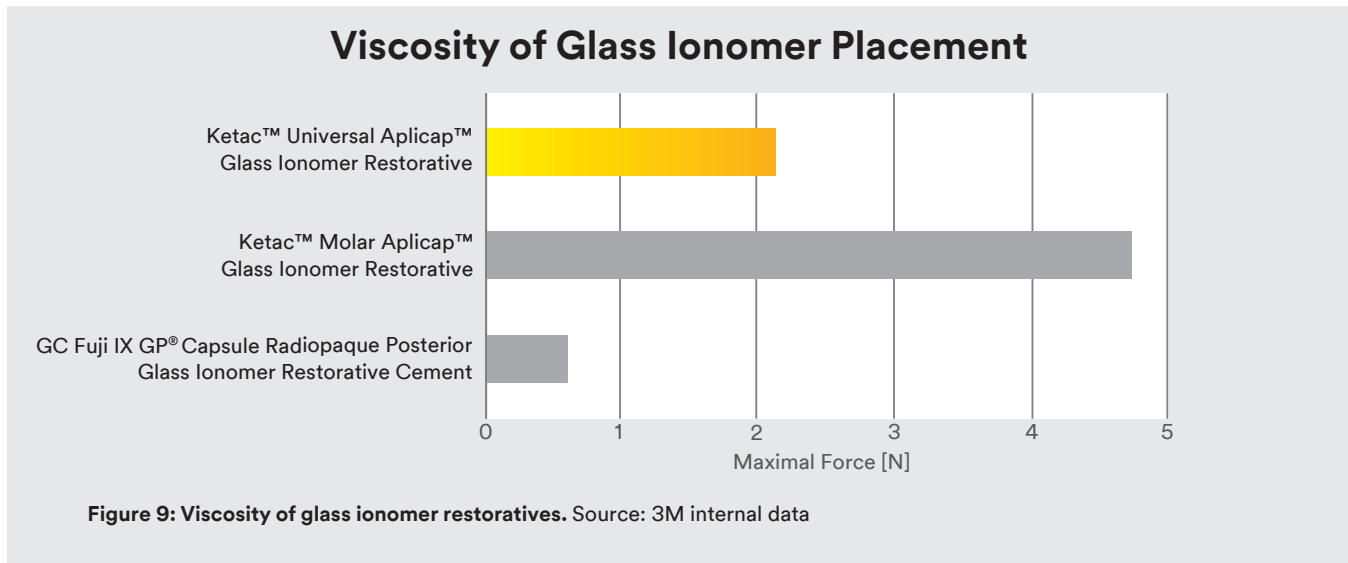
75% of dentists who evaluated Ketac Universal Aplicap restorative clinically stated that the low stickiness to instruments allows easy placement.

Note: See Clinical Performance Section for more details on the Application Test.

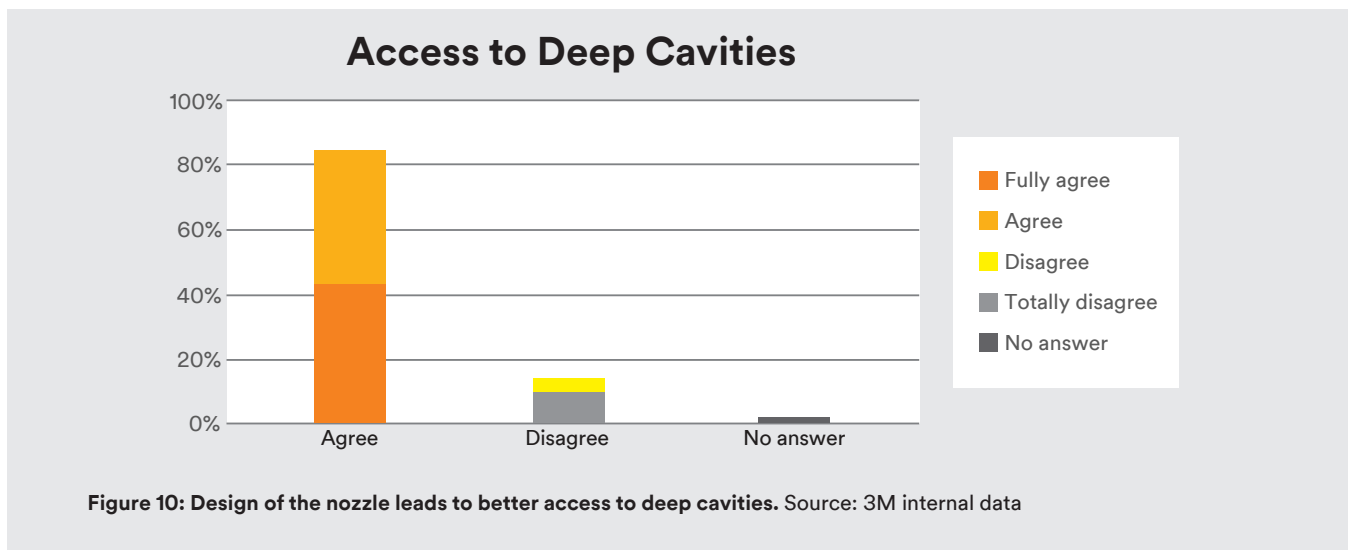
## Viscosity

This test mechanically simulates a ball-shaped metal plunger (sphere diameter: 3 mm, speed: 5 mm/sec.) placed onto the restorative material during its setting phase. The force needed to move the ball a certain distance (3 mm) into the paste is measured. The higher this force is, the higher the viscosity of the tested material.

Ketac™ Universal Aplicap™ Glass Ionomer Restorative has a medium viscosity.



**84% of dentists who evaluated Ketac Universal Aplicap restorative clinically agreed or fully agreed that the design of the nozzle leads to better access to deep cavities. The viscosity is lower than Ketac™ Molar Aplicap™ Glass Ionomer Restorative, enabling the extrusion of the mixed paste through the new tapered nozzle for better access to the cavity.**



**Note:** See Clinical Performance Section for more details on the Application Test.

## Fluoride Release

Ketac™ Universal Aplicap™ Glass Ionomer Restorative releases fluoride continuously over 24 months.

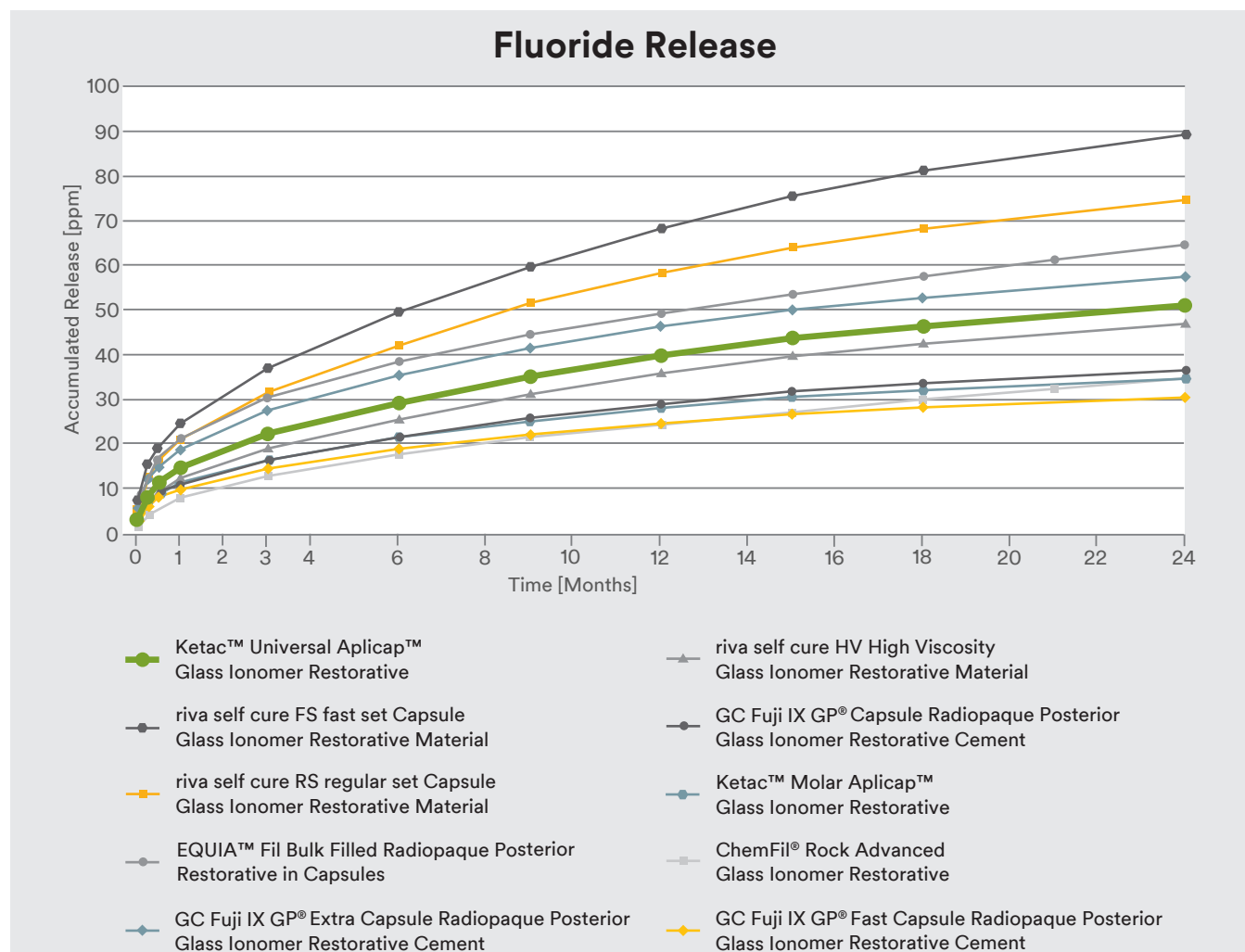


Figure 11: Accumulated fluoride release over 24 months. 3M internal data



**Ketac Universal Aplicap restorative releases a higher amount of fluoride than several glass ionomer capsules at least over a period of 24 months, including riva self cure HV Capsule, GC Fuji IX GP Capsule, Ketac™ Molar Aplicap™ Glass Ionomer Restorative, ChemFil Rock Capsule and GC Fuji IX GP Fast Capsule.**

## Resistance to Staining

To test stain resistance, samples were kept in water for 24 hours and then placed in a standardized coffee solution for 7 days at 36°C. By comparing the color values after the storage in water with the values measured after storage in coffee, the difference—or  $\Delta E$  value—is determined for each group.

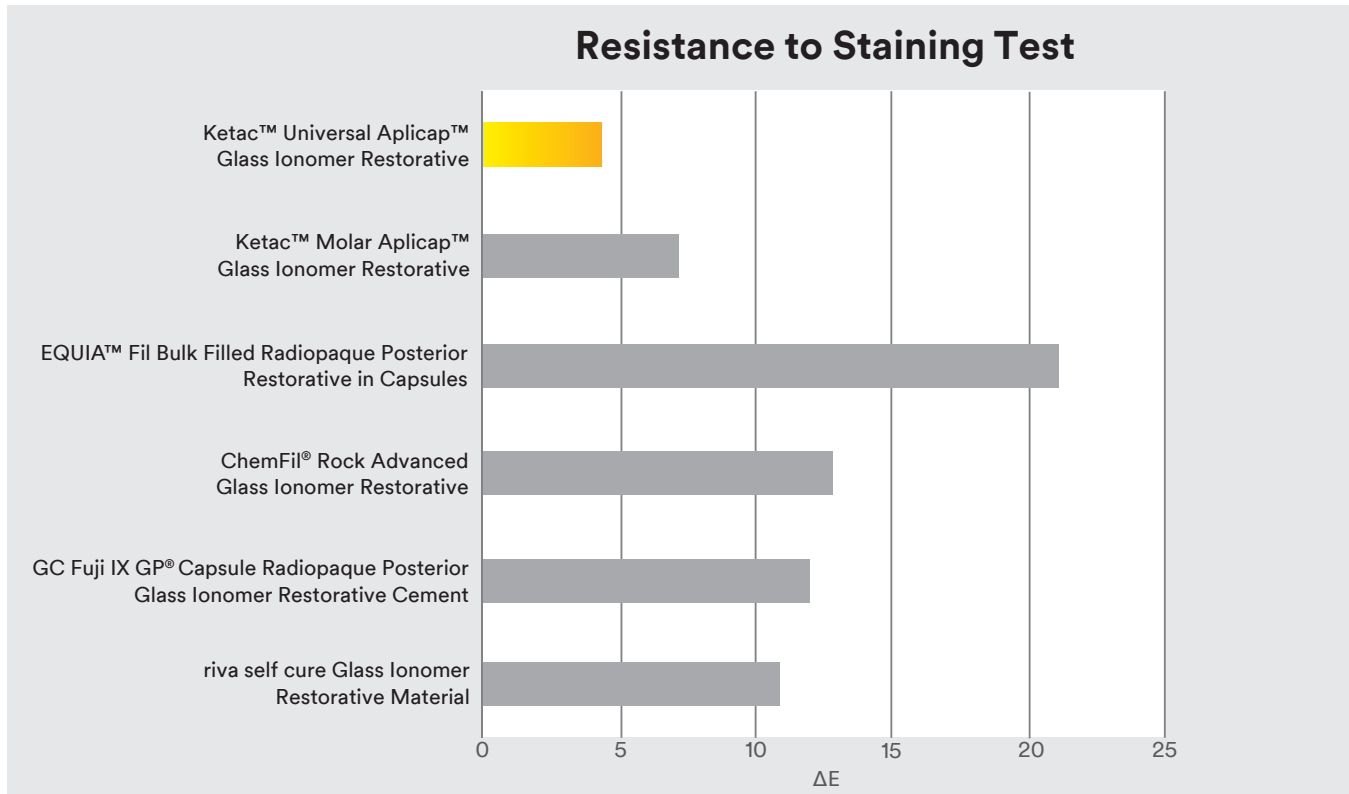


Figure 12: Change in color due to storage in coffee solution for 7 days. Source: 3M internal data

To maintain their aesthetics, restoratives must be resistant against staining. Food and beverages can be a major source of staining.



**Ketac™ Universal Aplicap™ Glass Ionomer Restorative resists coffee staining better than GC Fuji IX GP Capsule, EQUIA Fil Capsule, riva self cure Capsule and ChemFil Rock Capsule.**

# External Studies

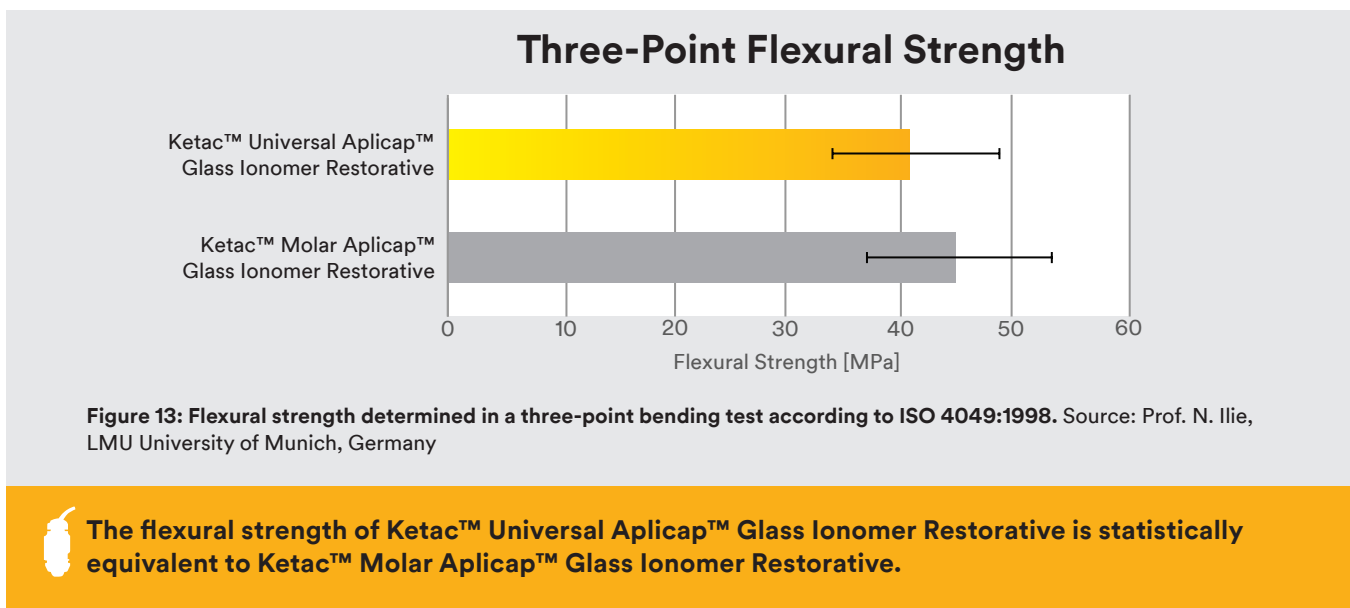
## Summary of Results

Properties	Measured values for Ketac™ Universal Aplicap™ Glass Ionomer Restorative	Institution conducting the study
Flexural strength	41.1 ± 7.3 MPa	LMU University of Munich
Martens hardness	769.6 ± 64.6 N/mm <sup>2</sup>	LMU University of Munich
Vickers hardness	91.6 ± 7.4 N/mm <sup>2</sup>	LMU University of Munich
Sliding wear	114.6 ± 25.0 μm	University of Regensburg

## Flexural Strength

The specimens were loaded until failure in a universal testing machine in a three-point bending test device.

The independent t-test reveals no significant difference between both analyzed materials.



## Surface Hardness

To test surface hardness, a test load was placed onto a sample of material. The test load was a controlled force that was increased and decreased with constant speed between 0.4 mN and 500 mN. The load and penetration depth were continuously measured.

The Universal hardness (Martens hardness) is defined as the test force divided by the apparent area of the indentation under the applied test force.

From a multiplicity of measurements, a conversion factor between Universal hardness and Vickers hardness was calculated so that the measurement results could be reported in the more familiar Vickers hardness (Diamond Pyramid Hardness) units.

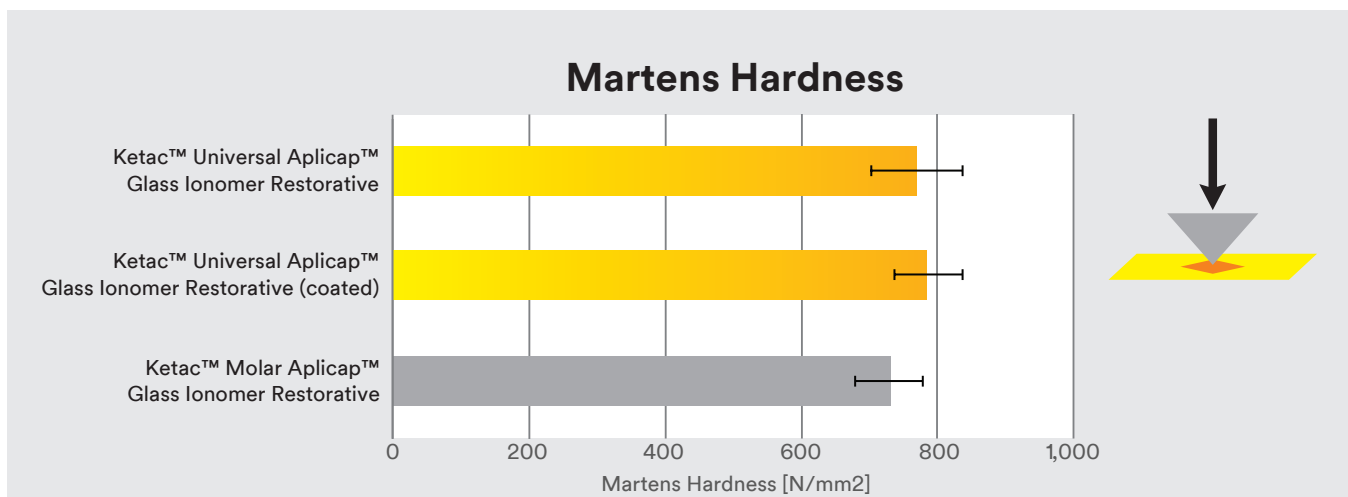


Figure 14: Martens hardness according to DIN 50359-1:1997-10. Ketac™ Universal Aplicap™ Glass Ionomer Restorative sample coated with Scotchbond™ Universal Adhesive. Source: Prof. N. Ilie, LMU University of Munich, Germany

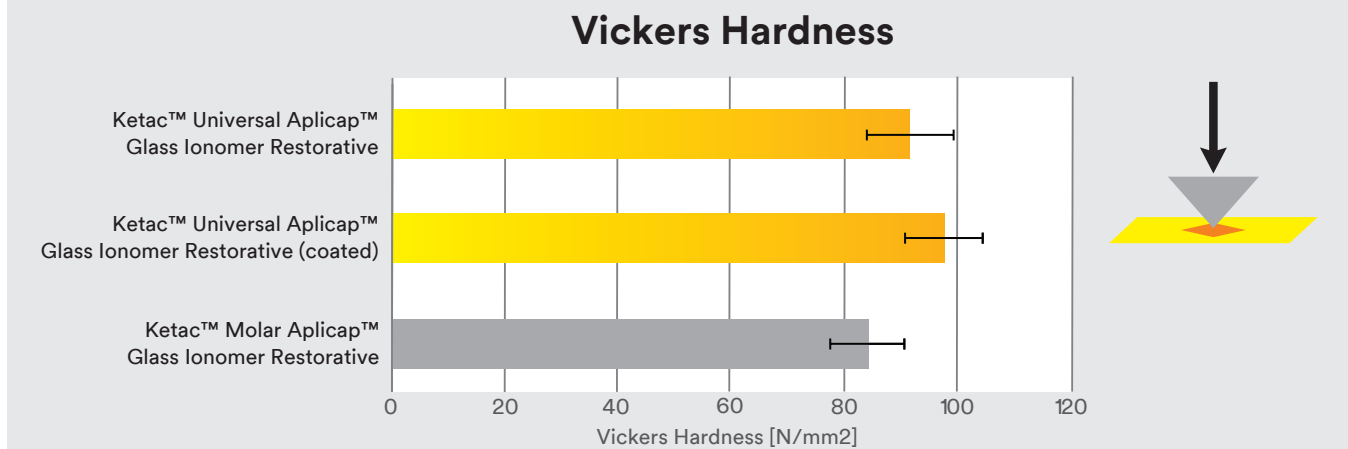


Figure 15: Vickers hardness according to ISO 4049:1998. Ketac™ Universal Aplicap™ Glass Ionomer Restorative sample coated with Scotchbond™ Universal Adhesive. Source: Prof. N. Ilie, LMU University of Munich, Germany



The surface hardness of Ketac™ Universal Aplicap™ Glass Ionomer Restorative is statistically equivalent with or without coating to Ketac™ Molar Aplicap™ Glass Ionomer Restorative.



## Sliding Wear Test

For simulation of standardized wear, specimens were loaded in a linear sliding wear process without antagonistic impact. Steatite balls (magnesium silicate, n=8; d=3 mm) were used as antagonists. Afterwards, the vertical depth of substance loss [ $\mu\text{m}$ ] of the different samples was determined using a 3D laser measuring system.

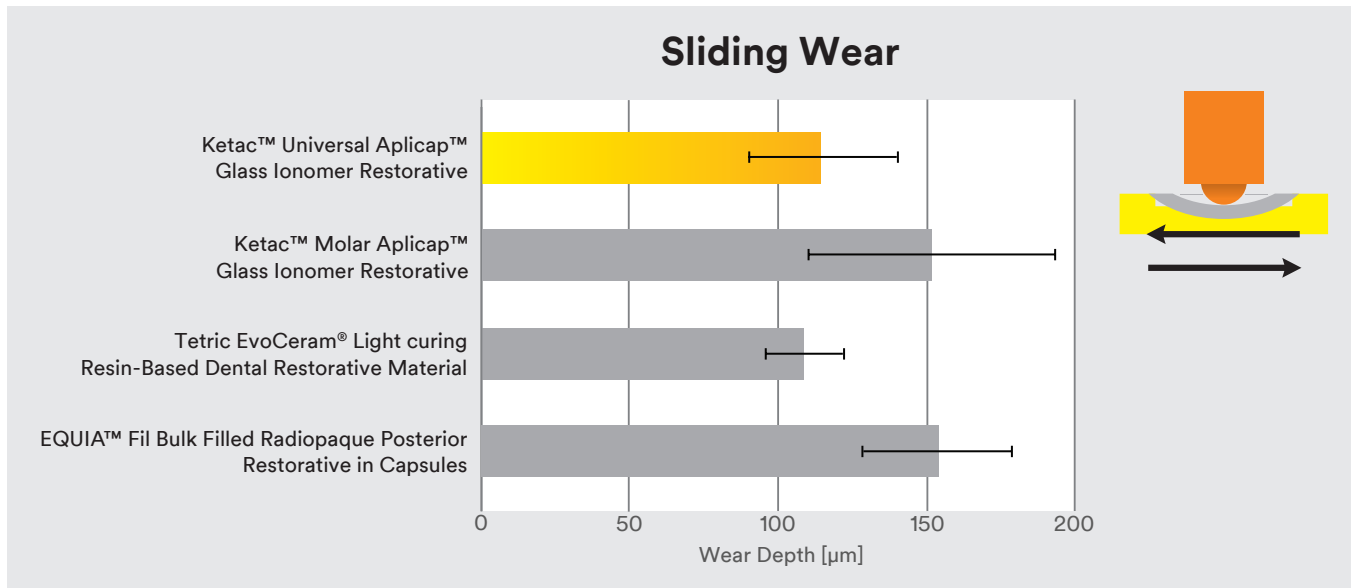


Figure 16: Wear depths measured in Sliding Wear Test. Source: Prof. M. Rosentritt, University of Regensburg, Germany

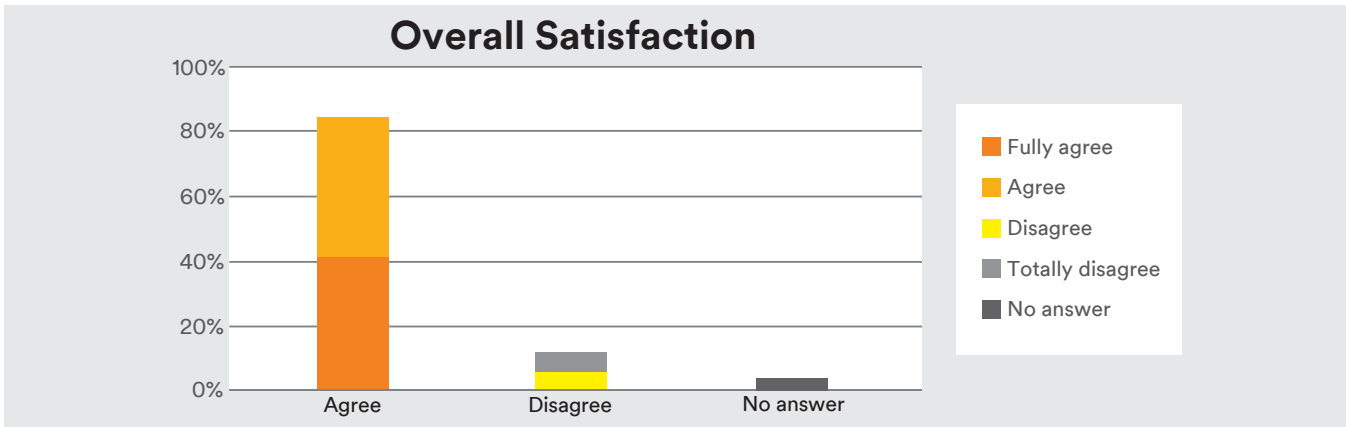


**The lower the wear, the better the wear resistance. The study showed lower wear results for Ketac™ Universal Aplicap™ Glass Ionomer Restorative compared to Ketac™ Molar Aplicap™ Glass Ionomer Restorative and EQUIA Fil, and comparable results to the composite Tetric EvoCeram.**

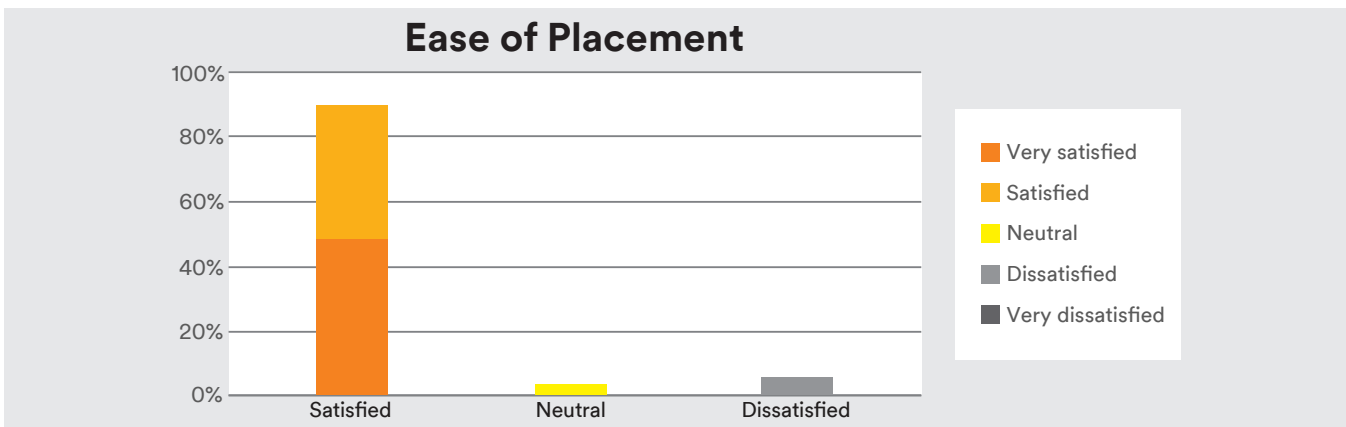
# Clinical Performance

## Application Test Results

965 restorations were placed by 51 dentists from Germany and the UK using Ketac™ Universal Aplicap™ Glass Ionomer Restorative in their offices. The dentists then evaluated the in vivo performance of the material after the trial period of six weeks.

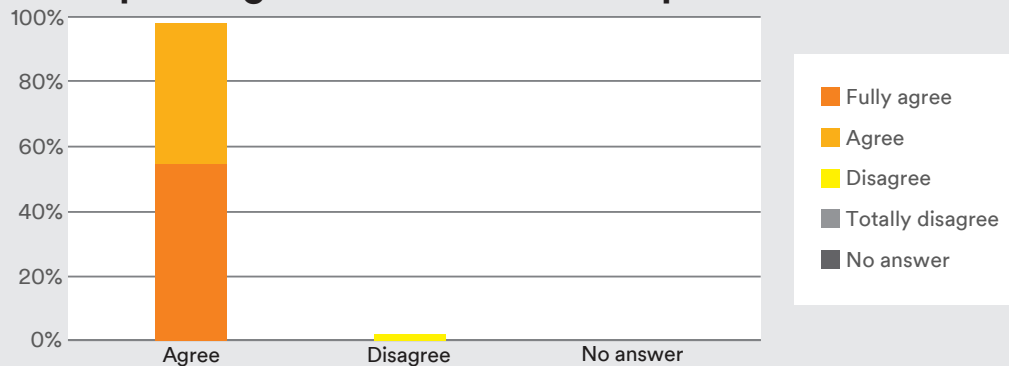


**80% of dentists who used Ketac Universal Aplicap restorative clinically are satisfied or very satisfied with the overall handling of the material.**



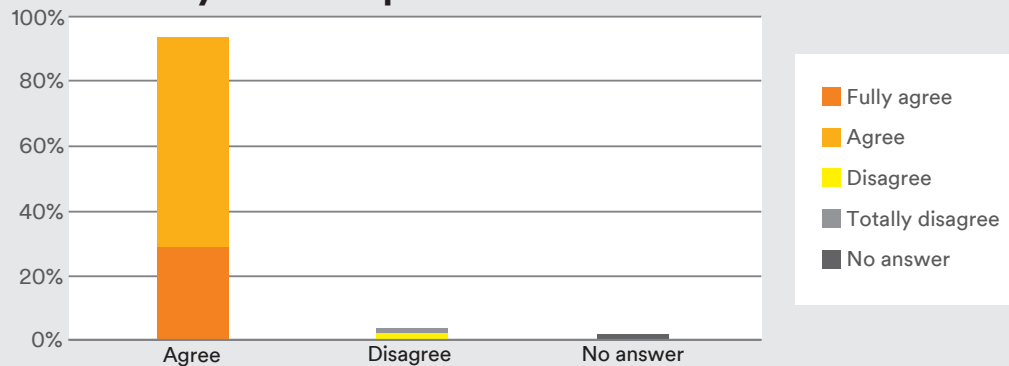
**90% of dentists who used Ketac Universal Aplicap restorative clinically stated that they are satisfied or very satisfied with the ease of placement.**

### Dispensing Material from the Capsule



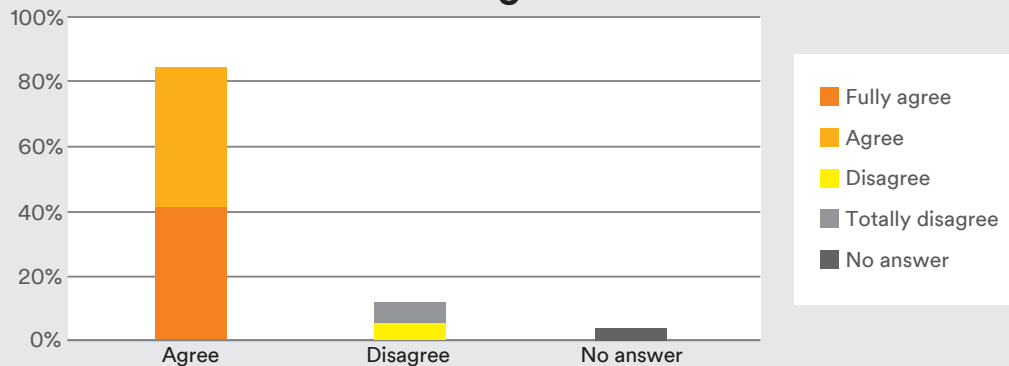
 50 out of 51 dentists (98%) who evaluated Ketac™ Universal Aplicap™ Glass Ionomer Restorative clinically believe that dispensing the material from the capsule is easy.


### Easy One-Step Bulk Placement



 According to 94% of dentists who evaluated Ketac Universal Aplicap restorative clinically, Ketac Universal Aplicap restorative enables an easy one-step bulk placement.

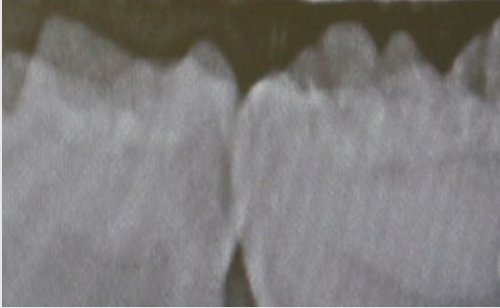
### Time Saving



 According to 84% of dentists who evaluated Ketac Universal Aplicap restorative clinically, Ketac Universal Aplicap restorative leads to time saving compared to using glass ionomer restoratives that require conditioning and glazing.

# Clinical Case

Treatment of a 6-year-old patient under general anesthesia with caries on deciduous mandibular molars.



**Image 1.** X-ray of deciduous teeth. Proximal lesion visible.



**Image 2.** Initial situation in vivo before treatment. Mandibular primary molars with caries lesions.



**Image 3.** Caries removal. Minimally invasive preparation: caries-free areas of enamel and dentine are left in the center of the cavity.



**Image 4.** Tofflemire Matrix fixed by a wooden wedge.



**Image 5.** Bulk placement of Ketac™ Universal Aplicap™ Glass Ionomer Restorative into the cavity.



**Image 6.** Restoration before finishing and polishing.



**Image 7.** Surface adjustment and excess removal with a fine diamond bur.



**Image 8.** Final Ketac™ Universal Aplicap™ Glass Ionomer Restorative restorations.

# Questions and Answers

## 1. What are the benefits of Ketac™ Universal Aplicap™ Glass Ionomer Restorative vs. conventional glass ionomer restoratives?

- 1-step placement: No need for conditioner/coating
- Extended indications for use: Long-term restricted stress-bearing Class I and Class II restorations\*
- Lower stickiness to metal instruments allows easy placement
- Better cavity adaptation

## 2. How is Ketac Universal Aplicap restorative different from previous Ketac™ products?

- No need for conditioner/coating
- Nicer aesthetics compared to Ketac™ Molar Aplicap™ Glass Ionomer Restorative
- Extended indications for use: Long-term restricted stress-bearing Class I and Class II restorations\*
- Improved filler composition leading to high mechanical properties, even with lower viscosity (compared to Ketac™ Molar Glass Ionomer Restorative)

## 3. Why doesn't Ketac Universal Aplicap restorative need a conditioner?

Ketac Universal Aplicap restorative has comparable adhesion values when used with or without a Ketac™ Conditioner. Furthermore, adhesion tests performed in-house show that these adhesion values are statistically comparable to the adhesion values of the clinically proven Ketac™ Molar Aplicap™ Glass Ionomer Restorative with Ketac™ Conditioner.

## 4. Can I still use a conditioner? Does it have any negative effects?

Ketac Universal Aplicap restorative is compatible with Ketac™ Conditioner. Using a conditioner does not lead to negative effects; however, it does not significantly change the adhesion values.

## 5. Why doesn't Ketac Universal Aplicap restorative need a coating?

The special filler composition-in combination with the co-polymeric acid used-and the accelerated setting performance lead to high compressive and flexural strength. In addition, the material exhibits high surface hardness values even in early maturation stages (within 10 minutes after the start of setting), thus surface hardness is high regardless of using a coating or not.

## 6. Can I use a coating? Does it have any effects?

Ketac Universal Aplicap restorative can be coated using Ketac™ Glaze or Scotchbond™ Universal Adhesive. Applying a coating will make the surface of the restoration glossier for the first hours; nevertheless, the performance of the material will remain unchanged.

**7. What are the benefits of the new Aplicap™ capsule compared to the Ketac™ Molar Aplicap™ Glass Ionomer Restorative capsule?**

Better reach into deep cavities due to the longer, more conical nozzle.

**8. Is the new capsule still compatible with the Aplicap™ Applier?**

Yes.

**9. Do I need to light cure Ketac™ Universal Aplicap™ Glass Ionomer Restorative?**

Ketac Universal Aplicap restorative is a traditional glass ionomer restorative with a self-cure (acid-base) mechanism, so light curing is not necessary.

**10. What is the mixing time?**

Use a high frequency mixing device (4,300 RPM).

- 8 seconds for RotoMix™ Capsule Mixing Unit
- 10 seconds for other high frequency mixing devices operating at a frequency of 4,300 RPM.

**11. What is the working time?**

1 minute 40 seconds working time (after mixing step has been completed).

**12. How long is the shelf life of the material?**

36 months shelf life.



## **3M.com/KetacUniversal**



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