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# Calibra™

## *esthetic resin cement*

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With the compliments of

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**TECHNICAL MANUAL**

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## Introduction

Restorative dentistry has witnessed the development of a wide variety of materials, methods, and technologies during the latter half of the $20^{th}$ century. In particular, advances in ceramic technology have made possible strong and easily fabricated porcelains for indirect restorations such as crowns, inlays, onlays, and veneers. At the same time, advances in polymer technology have led to adhesives and luting cements that bond these ceramics to the existing dentition. As the properties of both ceramics and luting cements have improved, there has been an ever-growing emphasis placed not only on the durability but also on the esthetics of the restorations. Furthermore, the growth in the patient population for many of these new restorative procedures has given rise to an increasing demand for cements that are easy for the clinician to use, both to shorten the procedure time and also to allow a wider variety of clinical applications. It is with these trends in mind that ***Calibra™ Esthetic Resin Cement*** has been developed.

# Types of Luting Cements

Many different chemistries have been employed to hold restorative and prosthetic dental devices to natural dentition. Many of these approaches are summarised in the sections that follow, along with their advantages and disadvantages.

### ***Zinc Phosphate Cement***

One of the earliest luting cements was zinc phosphate. This cement sets by an acid-base reaction between zinc oxide/magnesium oxide powder and aluminium-buffered aqueous phosphoric acid.[1] Developed more than 90 years ago,[2] this was the luting cement of choice for precision castings because of its ability to gel in a relatively thin film. However, this material has a number of well-documented disadvantages, chiefly its water solubility and lack of adhesion directly to the tooth structure.[3] Further, its setting time is strongly influenced by small variations in the water content of the liquid component, spatulation time and temperature, and powder-liquid ratio,[3] so the quality of the resulting restoration can be very technique-sensitive.

### ***Zinc Oxide-Eugenol Cement***

A second luting formulation, zinc oxide-eugenol (ZOE), has been used quite extensively in provisional restorations. In ZOE cement, zinc oxide powder reacts with eugenol in an acid-base reaction to form a zinc-eugenol salt. The primary advantage of ZOE cement is its palliative effect on dental pulp tissue.[4] However it also is very technique-sensitive, in this case due to variable incorporation of water from the atmosphere that causes variations in setting time.[4] Additionally, its low strength makes it unsuitable for permanent restorations.

### ***Zinc Silicophosphate Cement***

Zinc silicophosphate cements (ZSP) may be used by the clinician for indications similar to those of zinc phosphate cements. ZSP cements consist of a silicate glass and zinc oxide powder, and an aqueous phosphoric acid liquid. While it is stronger and more transparent than zinc phosphate cement, other more esthetically pleasing luting cements such as resin or glass ionomer cements have superseded it.[1]

***Silicate Cement***

Silicate cement is a powder-liquid system also. The powder consists of finely ground acid-soluble glass made of silica, alumina, lime, and fluoride salts. The liquid consists of an aqueous solution of phosphoric acid. When the components are mixed, the liquid dissolves a portion of the surface of the powder particles to form aluminium phosphate, which binds the cement together. Fluoride salts are dispersed throughout the matrix but do not take part in the gel structure. Fluoride ions can therefore leach continuously into the surrounding dentition. However the relatively low pH of the cement, even after weeks in the restoration, can lead to severe pulpal irritation.[1] This in part explains why silicate cement is not in widespread use as a luting agent today.

***Zinc Polycarboxylate Cement***

The first adhesive luting material,[1,5] zinc polycarboxylate cement was introduced in the 1960's.[2] In this system, zinc oxide and magnesium oxide powders partially dissolve into an aqueous solution of polyacrylic acid. Ions released during dissolution react with the acid groups of multiple polymer chains, effectively crosslinking the polymer in a gel structure. The mechanism of adhesion is believed to involve a reaction between the acid groups of the polymer and the calcium and phosphate ions in the tooth structure.[1] The greatest advantage of zinc polycarboxylate cement is its biocompatibility with dental pulp,[1] but its significant plastic deformation makes it relatively unsuitable for locations under high masticatory stress and for long-span prostheses.[2] Moreover, this cement exhibits an early rapid increase in film thickness that may interfere with the proper seating of a casting.[2]

***Glass Ionomer Cement***

Glass ionomer cements (GIC), first introduced in the 1970's, are direct descendants of silicate and polycarboxylate cements.[2] The liquid component of GIC consists of an aqueous solution of a polyacid and the powder component consists of a fluoride-containing silicate glass. Upon mixing, the polyacid partially dissolves the silicate glass, releasing ions that chelate the acid groups of multiple polyacid chains to gel the material. Fluoride ions, which are present but do not participate in the gelation reaction, can leach from the cement into the tooth structure. Further, acid groups not already chelated by ions from the silicate glass are free to chelate calcium and phosphate ions in the tooth structure and thereby develop an adhesive bond.

GIC combines the fluoride release of silicate cement with the biocompatibility of polycarboxylate cement. This material is also self-adhesive to tooth structure.[1] These properties represent the greatest advantages of glass ionomers. On the other hand, GIC is highly susceptible to attack by moisture, particularly in the early stages of setting.[2] Glass ionomers do not develop full strength until 24-72 hours after placement, and marginal integrity can be degraded by early exposure to saliva and water. Therefore the tooth preparation must be thoroughly dried prior to cementation. However, over drying or desiccation of the dentin may explain the relatively high incidence of post-operative sensitivity associated with restorations seated with GIC.[2] Thus, this cement can be technique sensitive.

## ***Resin-Modified or Resin-Reinforced Glass Ionomer Cement Compomer Cement***

Resin-modified glass ionomer cement (RMGI or RRGI) uses a different approach to overcoming the limitations of GIC while at the same time retaining self-adhesion, biocompatibility, and fluoride-release properties. Here, the polyacid contains acrylate functional groups and, when mixed with the glass powder, forms a polyacrylate salt in an acid-base reaction. Initiators in the formulation can then start a free-radical polymerisation which covalently crosslinks the polyacrylate salt and significantly strengthens the cement. Compomers can be described as polyacid-modified composite resins. The polyacid is created in place by the polymerisation and crosslinking of an acid-functional dimethacrylate monomer. In either case, these cements generally have fluoride release and adhesion to tooth structure similar to that of GIC.[2] Additionally, because of the covalent crosslinking they are less susceptible to water attack and less soluble than GIC.[2]

A significant advantage of some RMGI and compomers over conventional GIC is command-cure. A photoinitiator may be incorporated into the cement in order to allow the clinician to place the cement and then cure it at the appropriate time with visible light. This gels the cement to an intermediate strength sufficient to hold the restoration. The cement fully cures in an ionomer reaction over the next several days as water is slowly incorporated into the cement matrix. Water absorption by the ionomer functionality of the cement is augmented by water absorption from the slightly hydroscopic resin functionality, sometimes leading to long term expansion of the cement[1,2]. Though this water sorption may compensate for polymerisation shrinkage, continued sorption and dimensional increase, coupled with very high adhesion to tooth structure and ceramics, may lead to fracture of all-ceramic crowns.[5]

## ***Resin Composite Cement***

Resin composite cements typically consist of Bis-GMA resin monomer, a glass filler, a chemical initiator (for self-cured and dual-cured systems), and a photoinitiator. ***Calibra Esthetic Resin Cement*** is an example of a resin composite cement, the strongest of all types of luting cements available today.[5]

Polymerisation is through a free-radical crosslinking reaction of the monomer to form a three-dimensional network. Dual-cured materials normally are delivered as a paste-paste system (base and catalyst), which makes mixing easy. The photoinitiator allows a command-cure in areas where light is accessible, and the chemical initiator ensures thorough curing in areas where light is not accessible, for example under full-coverage metal and PFM crowns and endodontic posts. The glass filler provides high compression strength and resistance to tensile fatigue. Furthermore, these materials are practically insoluble in the oral environment. The filler also provides an improvement in wear resistance over GIC and RMGI cements.

By themselves, resin cements do not bond directly to tooth structure. However resin bonding agents such as ***Prime & Bond*® *NT*** allow resin cements to adhere to the native tooth structure and hold restorations strongly in place. Also, while they do not have the level of fluoride release available in a GIC, RMGI cement, or compomer, the incorporation of fluoride glass as the filler does allow resin cements to release fluoride.

## The Ideal Luting Cement

A number of factors are involved in determining the quality of a luting cement. They may be grouped into four broad categories: biocompatibility, mechanical integrity, esthetic characteristics, and ease of handling.

### ***Ideal Biocompatibility***

The most important of these characteristics is biocompatibility. A luting cement must be nontoxic and have a low potential for allergic reactions in the body. Further, it must show little interaction with body tissues and fluids. It therefore should be easy on the pulp, which should lead to little or no sensitivity. It should also prevent bacterial microleakage at marginal interfaces. Ideally, the cement would be anticariogenic (fluoride releasing) and antimicrobial, and actively inhibit plaque deposition.

### ***Ideal Mechanical Properties***

Another critical set of characteristics involves the mechanical properties of the cement. First and foremost, the cement must be capable of resisting functional forces over the lifetime of the restoration. It must have, therefore, sufficient strength to resist crushing and fracture, particularly in posterior applications where mastication forces will be greatest. It must also resist long term cyclic fatigue and plastic deformation (creep). The cement should adapt well at the margins of the restoration and maintain adhesion and marginal integrity over the lifetime of the restoration. It should adhere not only to enamel and dentin, but also to ceramics and metals. Ideally it will have thermal expansion and a thermal transfer rate identical to those of dentin and enamel, and will not shrink or expand during curing. And it should aid in preventing fracture of ceramic prostheses.

The cement should also resist degradation in the oral environment. In particular, it should be insoluble and resistant to water absorption. Further, it must be resistant to wear and insensitive to ultrasonic scaling. Finally, all properties should be unaffected by the wide swings in temperature often encountered in the oral environment.

### ***Ideal Esthetic Characteristics***

The esthetic characteristics of luting cements have become increasingly important in restorative dentistry as the biocompatibility and mechanical properties of dental porcelains and luting cements have improved. A luting system should contain a variety of shades that spans the range of shades of natural teeth. This range must contain at least one opaque shade to hide posts and underlying discoloration, and a transparent shade that will virtually disappear under ceramic and not affect the appearance of the resulting restoration. All shades must be stable, resisting shifts in colour both in the short term (2-4 weeks) and in the long term (1 year and beyond), and not be subject to staining at the margins.

## ***Ideal Handling Properties***

Finally, an ideal luting cement must have handling properties that make it easy for clinicians and assistants to use. It must have a very low film thickness, allowing for good adaptation of the restoration to the preparation in order to avoid incomplete seating. It must have a selectable viscosity appropriate to the type of prosthesis being placed: low, for easy hydraulic flow under full-coverage crowns and onlays; higher and more thixotropic for inlays and veneers. In either case, the cement should hold the restoration where it was placed and not be subject to rebound or sliding.

The cement should be command-cure, allowing the clinician to gel the material immediately once the restoration is properly placed. In applications where only light curing is desired, the cement should be usable directly from its package without mixing. On the other hand, when self-cure or dual-cure is needed, both cement components should be in identical packages to make metering of dosages easy. The self-cure working time after mixing of the components should be sufficiently long to allow placement of one or more prostheses. But, the set time must be short enough to minimise waiting and allow rapid development of acceptable physical properties when light curing is not appropriate (under PFM crowns, for example). Marginal cleanup of excess cement must be easy with little smearing or stringiness. And the material should be radiopaque for future examination.

Finally, for applications where appearance is critical, a set of try-in pastes should be available. These pastes must be close matches to the cured cement shades but should be easily water-washable. They should be sufficiently viscous to hold veneers temporarily while their appearance is being checked.

# Calibra Esthetic Resin Cement

## *Indications*

***Calibra Esthetic Resin Cement*** is an all-purpose luting cement designed to be used in a broad variety of clinical applications. It is indicated for adhesive cementation in all of the restorative and prosthetic procedures performed in contemporary restorative dentistry: ceramic, porcelain, and composite crowns; inlays, onlays, and veneers; all-metal crowns, bridges, inlays and onlays including precious, semi-precious, and non-precious metals; PFM crowns and bridges; prefabricated and cast posts; and resin-bonded retainer bridges (Maryland bridges).

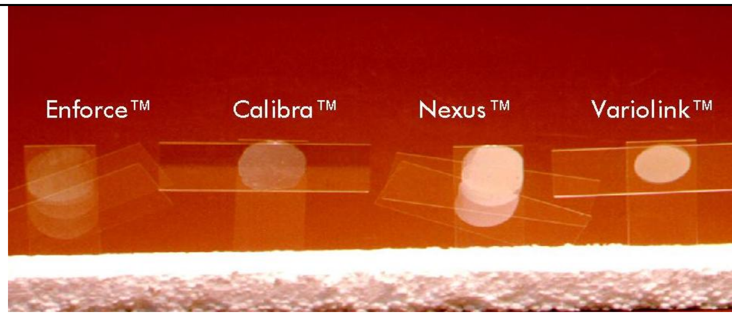
## *Components of the Calibra System*

The complete ***Calibra Esthetic Resin Cement*** system includes five shades of base paste (Translucent, Light, Medium, Dark, Opaque); two unpigmented catalyst pastes, in high and regular viscosities; and try-in pastes in five shades that correspond to those of the base shades. These try-in pastes facilitate the selection of the final cement shade. Also included are ***Prime & Bond NT*** single-bottle bonding agent, the ***Self-Cure Activator*** for the bonding agent, and a one-component ceramic silanating agent.

## *Calibra Handling Characteristics*

***Calibra Esthetic Resin Cement*** is a paste-paste system in which both the catalyst and base pastes are delivered from push-type syringes making dose metering easy. The cement may be used in either visible light cure (VLC) mode or dual cure mode. When used in VLC mode, the base pastes may be applied directly to the restorations without mixing. These pastes are designed to be thixotropic, in other words to have low viscosity when flowing under applied pressure but high viscosity when that pressure is relieved. This allows for smooth and easy placement of restorations without rebound or sliding prior to curing. Excess cement at the margins may be removed easily, with no smearing or stringiness. The cement is cured through the restoration using readily available high output dental curing lights.

A graphic demonstration of the thixotropic nature of the ***Calibra*** base pastes can be seen in Figure 1. Here, approximately equal quantities of several VLC cements were placed at the ends of several glass slides oriented horizontally on a bench top. An additional glass slide was pressed onto each cement to make a sandwich in the shape of a "T." The glass slides were moved to the vertical position and a flash photograph taken immediately, then another taken one minute later in a double exposure. Clearly, the ***Calibra*** sample did not move while thinner, less thixotropic cements (for example, Nexus) moved considerably.




**Fehler! Textmarke nicht definiert.**

**Figure 1:** Thixotropic behaviour of Calibra base paste and other resin composite cements

Used in dual cure mode, ***Calibra*** base paste is mixed in a 1:1 ratio with ***Calibra*** catalyst paste. This catalyst, which when mixed with the base allows curing of the cement through light initiation or chemical self-cure in the absence of light, is available in two viscosities. The regular viscosity catalyst blended with any of the base pastes will create a dual cure cement that has a thin or runny consistency, useful in applications where a low-viscosity cement is needed to allow hydraulic flow from under a restoration as it is seated. On the other hand, the high viscosity catalyst paste blended with one of the base pastes forms a dual cure cement with stiffer consistency similar to that of the base paste alone. This stiffer cement is useful in applications where the thixotropic nature of the base is desired in a self-curing material. Both catalysts provide a working time of at least 2'30" at room temperature and a set time of no more than 6 minutes after mixing starts.

Note that the ***Calibra*** base and catalyst pastes are designed to be mixed at a 1:1 ratio. While the dual-cure chemistry is relatively insensitive to small deviations from this ratio, larger deviations should be avoided. In particular, **reducing** the catalyst content significantly will **reduce** the working and setting times of the cement, and not increase them as some might expect. Furthermore, changes to the ratio of catalyst to base in the mixed cement can have adverse effects on the strength of the finished restorations. It is therefore recommended that clinicians meter as close to the same quantities of the two pastes as possible when using the dual-cure system.

## ***Esthetic Characteristics***

***Calibra Esthetic Resin Cement*** has been formulated specifically to provide the clinician with outstanding esthetic characteristics. The base pastes are available in five shades, that span the shade range typically observed clinically. The system includes a Translucent shade designed to maintain the existing natural shading of the dentition and the porcelain. Also included in the system is an Opaque shade to cover underlying posts or discoloration in the tooth preparation. Light, Medium, and Dark shades provide the clinician with broad flexibility in matching the shade of the restoration to that of the surrounding teeth and the desires of the patient.

The broad shade coverage of the ***Calibra*** cement system is best shown in a three-dimensional plot of the shade space typically seen in restorative dentistry (Figure 2). In this graph, lightness is plotted on the vertical axis, while the blue-yellow and red-green axes form the horizontal plane of the space. ***Calibra*** evenly covers the range of shades seen clinically. (Note: The opaque shades are not shown on this plot – the pigment systems used to increase opacity tend to skew their placement on this graph and therefore cannot be compared easily to the non-opaque shades.)

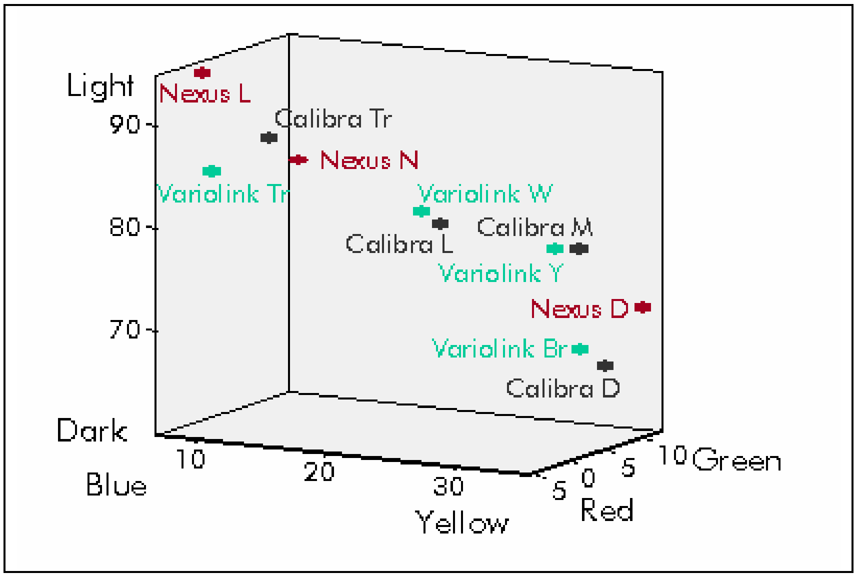



**Figure 2a:** View on the blue-yellow plane

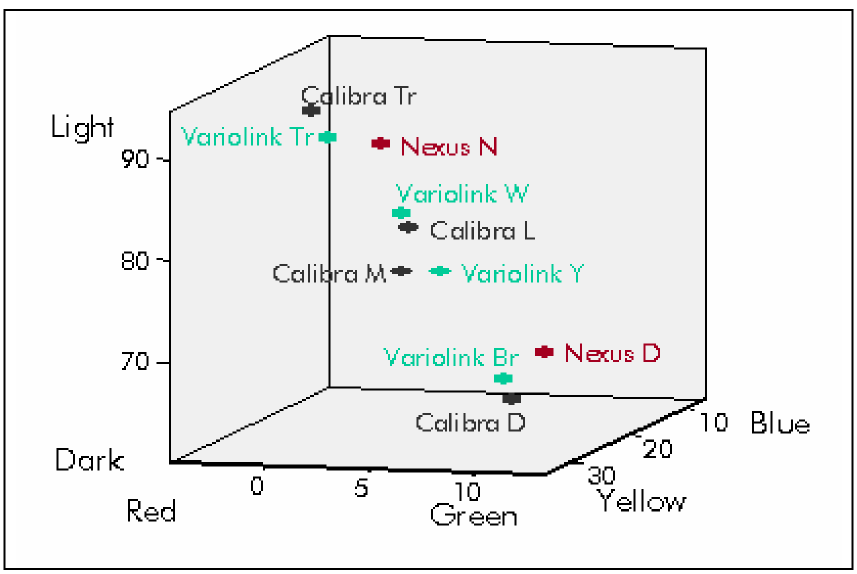



**Figure 2b:** View on the red-green plane

***Calibra*** has also been formulated with “Shade-Stable™ ” chemistry. The shade stability of a cement is its resistance to a shift in the shade once cured. All resin cements shift slightly once cured, invariably by darkening. Translucent shades tend to shift by the greatest amount, but as the shades themselves become darker the shift decreases until the darkest shades shift imperceptibly.

Shade stability is determined by comparing the L, a, b parameters from a Cielab Colour Eye instrument immediately on curing and then after three days of immersion in water at 37°C. The Cielab parameter "L" quantifies the lightness of the shade; the "a" parameter quantifies the shade in the red-green continuum, and the "b" parameter quantifies the shade in the blue-yellow continuum. The vector magnitude of the change is known as ΔE, and is calculated using the following equation:

$$\Delta E = \{(\Delta L)^2 + (\Delta a)^2 + (\Delta b^2)\}^{1/2},$$

where the prefix " Δ" represents "the change in." Upon direct viewing of a sample, the trained eye may detect a ΔE value of 1.5 - 2.0 units, while the average person can see a shift of about ΔE = 2-3 units. A ΔE value as large as 3.5 units may not be perceptible when the cement is used under a crown or veneer.

The ΔE value of ***Calibra Esthetic Resin Cement*** Translucent base paste is shown in Figure 3 compared to those of several other resin cements that have visible light curable pastes. This confirms that ***Calibra Esthetic Resin Cement*** is shade-stable.

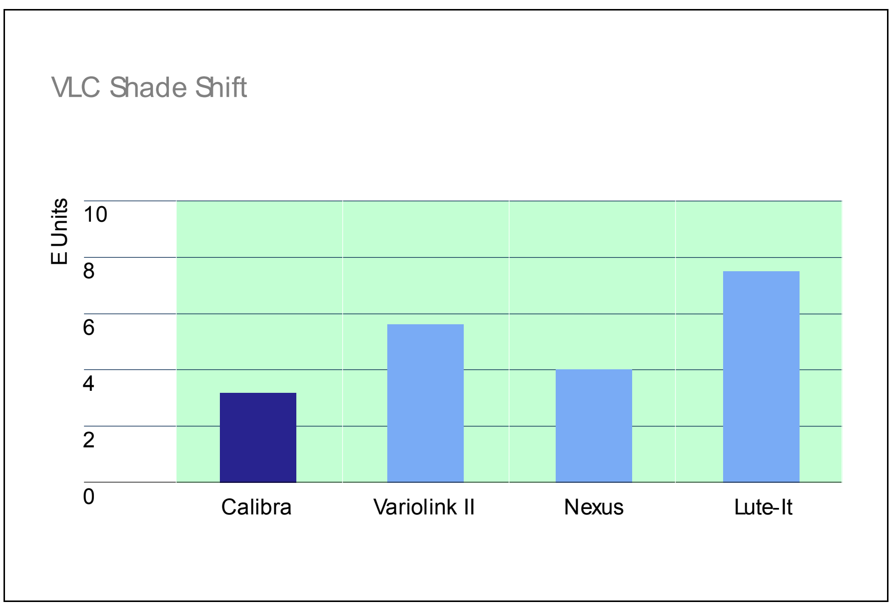



**Figure 3:** Shade shift for several VLC resin cements

## ***Physical and Mechanical Properties***

As might be expected from a resin cement, the mechanical properties of ***Calibra Esthetic Resin Cement*** are excellent. Further, barium and fluoride in the glass filler provide both radiopacity and fluoride-release to the cement. Details of the physical properties of the ***Calibra*** system are given in the sections that follow.

Crown Retention Strength The crown retention strength of a cement represents the force needed to remove a crown that has been cemented to a tooth preparation. Clinically it correlates to the likelihood that a crown cemented *in vivo* will be retained on the preparation.

The crown retention test method uses caries-free, mandibular premolars that have been prepared for castings and secured to an Instron Universal Test Machine (UTM). Uniform preparations are created in all teeth, castings are made, and Type III gold castings are cemented with regular-viscosity, self-cured cement according to each manufacturer's directions for use. A ring on the casting allows it to be pulled from the tooth in the UTM while measuring retention force in kilograms.

Figure 4 shows the retention force for several cement systems compared to ***Calibra Esthetic Resin Cement***. Clearly, ***Calibra*** is a leader in its ability to retain crowns.

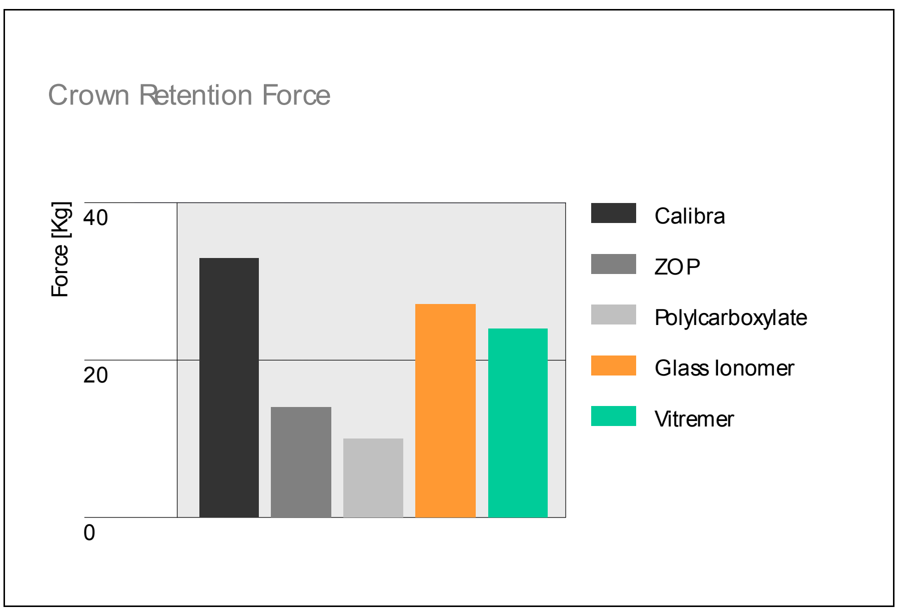



**Figure 4:** Crown retention force for several regular-viscosity luting cement systems. Data courtesy of Dr. C. Pameijer, U. Conn. School of Dentistry, Professor Emeritus

Consistency The consistency is a measure of the flow characteristics or "body" of the material. It corresponds to the amount of force needed to seat a restoration. It is measured by pressing a sample of known volume between glass plates under a common weight and at a well-defined temperature. The diameter in millimetres of the "pat" formed is the consistency, and lower numbers represent more viscous or stiffer materials.

The consistencies of several resin cements are compared in Figure 5. ***Calibra*** base pastes used in VLC mode (no catalyst paste) have body that is in keeping with superior stay-put character. In dual-cure mode two viscosities of cement are available – an easy-flow, runny cement and a stiffer, higher-body cement. Because the physical properties and chemistries of the two are similar, which viscosity of dual-cure cement will be used with each application is at the discretion of the clinician.

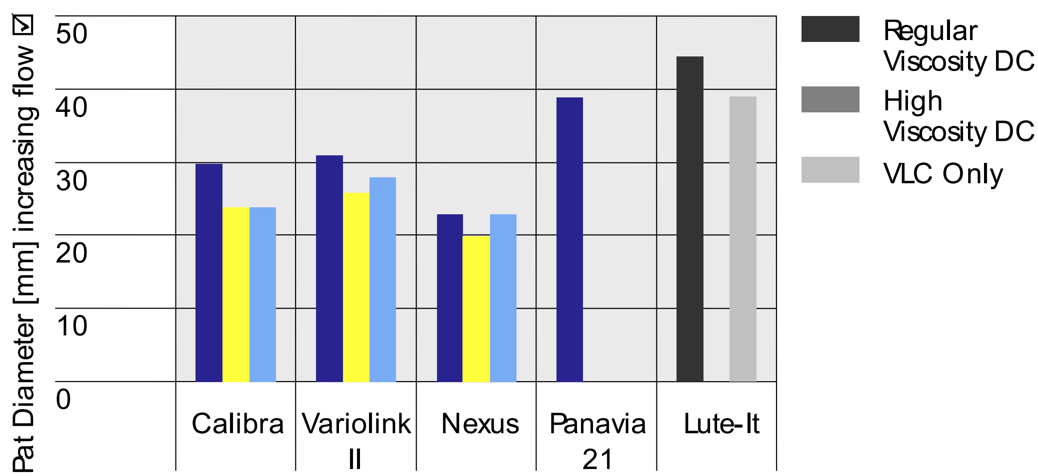



**Figure 5:** Consistency of Calibra Esthetic Resin Cement compared to that of several othe resin cements. Note that Panavia 21 is exclusively self-cured and has a single ciscosity, while Lute-It is not supplied with a high-viscosity catalyst.

Work Time/Set Time The work time after mixing of the components of a self-cure or dual-cure resin cement defines the window within which the cement can be manipulated before it begins to thicken and thereby present a risk of improper seating of the restoration. The set time is the time after mixing by which the cement will have hardened to a point where the restoration will be fully retained. It is the point of nearly complete crosslinking of the polymer.

The work time is determined by measuring the time from the start of mixing until perceptible thickening of the cement takes place. The set time is determined in the same experiment as the time after mixing when the cement cuts with a snap.

The ideal work time of a resin cement is long, and the ideal set time after seating the restoration is short. Since the work time must always be less than the set time, these two ideals are opposed to one another, so the cement should be designed to optimise both properties. ***Calibra Esthetic Resin Cement*** has a working time of at least 2.5 minutes and a set time of no more than 6 minutes.

As noted above, small variations in the ratio of pastes in the mixture will not affect the work and set times noticeably, but large deviations from the 1:1 ratio should be avoided. **Reducing** the catalyst component by a significant amount will **speed up** the setting reaction because of the chemical balance of the base paste in relation to the catalyst paste. Since changes of this type affect the setting chemistry, it is recommended that the pastes be mixed at a ratio of 1:1.

A comparison of the work and set times against those of other leading resin cements is shown in Figures 6 and 7.

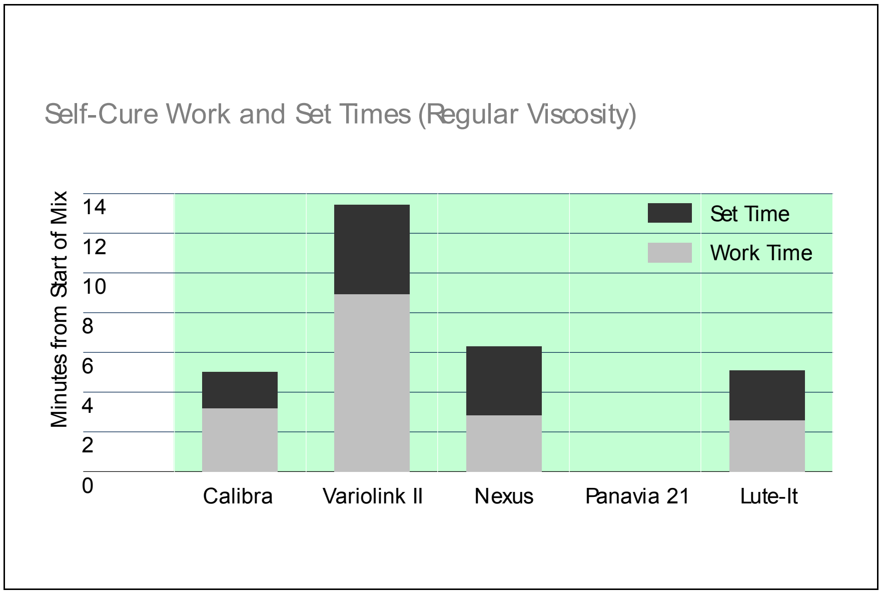



**Figure 6:** Self-cure work and set times of regular-viscosity resin cements. Note that Panavia 21 is strongly air-inhibited and does not set under the conditions of testing

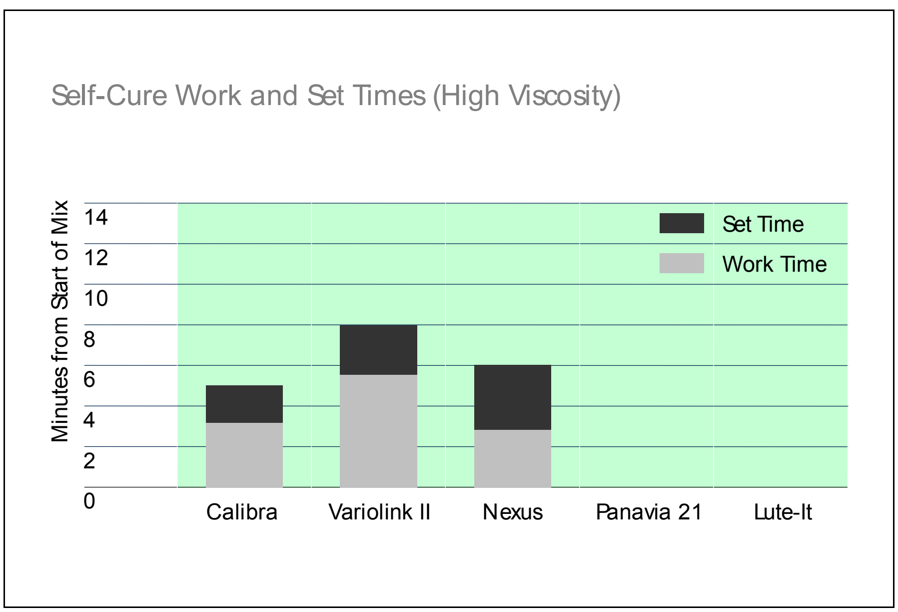



**Figure 7:** Self-cure work and set times of high-viscosity resin cements. Note that Panavia 21 and Lute-It are not available in high-viscosity versions

Flexural Strength and Modulus The flexural strength of a material is a measure of its ability to withstand cyclic bending stresses generated under mastication. It is particularly important with the thin films in which luting cements are normally found. Clinically, it correlates with fracture resistance, especially at the margins. The flexural modulus of a material is a measure of its stiffness in bending. Materials with high flexural modulus tend to be brittle while low modulus materials (<5000 MPa) tend to rebound and flex when stressed, possibly leading to debonding. Therefore a moderate modulus (5000-7000 MPa) coupled with a high flexural strength (>100 MPa) is desired for luting cements. ***Calibra*** presents the best combination of strength and elasticity for cement applications.

Both flexural strength and modulus are determined by subjecting a 2 mm by 2 mm by 25 mm bar sample of the material to three-point bending. Using an Instron UTM, a compressive force is applied and measured at the centre of the bar whose ends are positioned on two upright supports. The bending action on the bar produces a compression in the upper half of the bar and a tension in the lower half. This dual-stress condition simulates the stress distribution in the cement film under mastication.

In Figures 8 and 9, it can be seen that ***Calibra Esthetic Resin Cement*** has a very high flexural strength but a moderate flexural modulus.

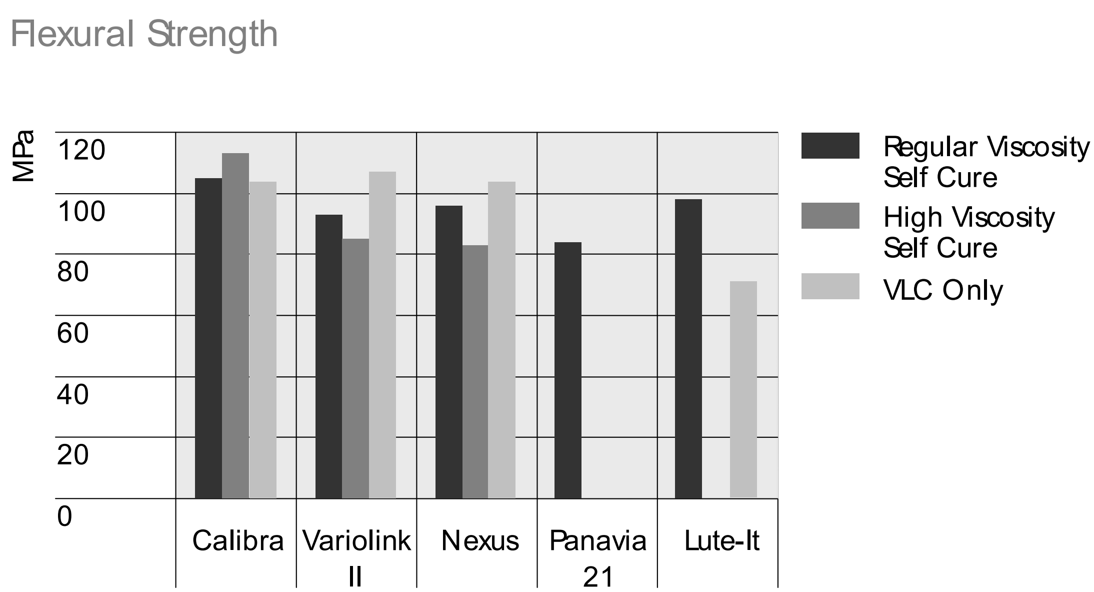



**Figure 8:** Flexural strength of several resin cements

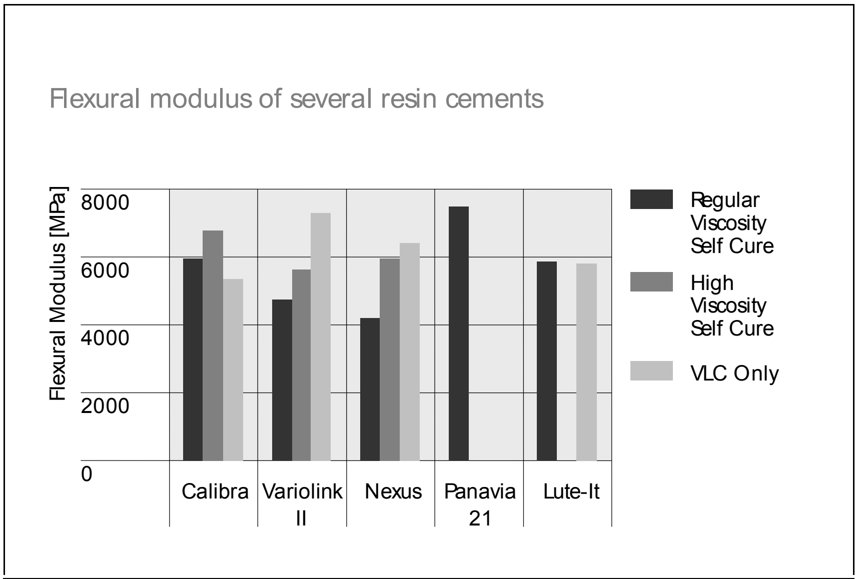



**Figure 9:** Flexural modulus of several resin cements

<u>Fracture Toughness</u> The fracture toughness of a material describes its ability to resist catastrophic propagation of cracks under applied mastication forces. Essentially, it is the amount of energy needed to continue the propagation of a crack caused by an inherent flaw within the material until fracture occurs. It is a critical property in relation to the margins of a restoration, where surface flaws are common. A higher value of fracture toughness implies a lower rate of marginal degradation. Note that a material having high fracture toughness is generally considered to be strong, but a strong material is not necessarily tough.

Fracture toughness is measured by using the notchless triangular prism (NTP) specimen method developed by N.D. Ruse[6]. The method uses the Instron UTM and a special test fixture to apply and measure the force required to initiate and propagate a fracture crack in the test material. The measured force, flaw depth, and specimen dimensional parameters are calculated in the determination of the fracture toughness value.

***Calibra Esthetic Resin Cement*** has a particularly high fracture toughness compared to other leading resin cements. See Figure 10.

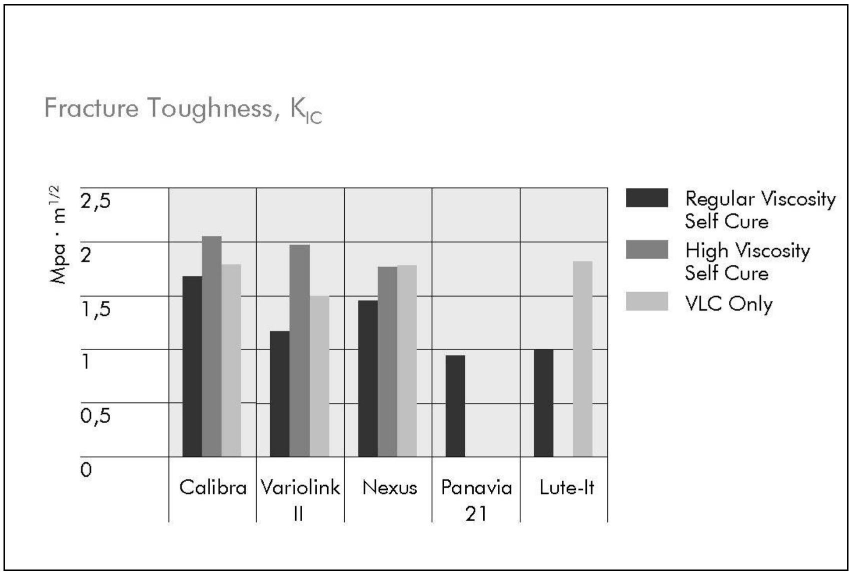



**Figure 10:** Fracture toughness of several self-cure resin cements

<u>Diametral Tensile Strength</u> (Figure 11) Diametral tensile strength is a measure of the material's resistance to cohesive failure when pulled apart. Clinically, it correlates roughly to such properties as crown retention.

The diametral tensile strength is measured by crushing a 3 mm diameter by 6 mm long sample of cured cement on an Instron Universal Testing Machine (UTM) along its diametral axis until fracture failure occurs. The stress of fracture is characteristic of the force needed to pull the material apart along its diametral plane

The diametral tensile strength of ***Calibra Esthetic Resin Cement*** is comparable to that of other resin cements available today.

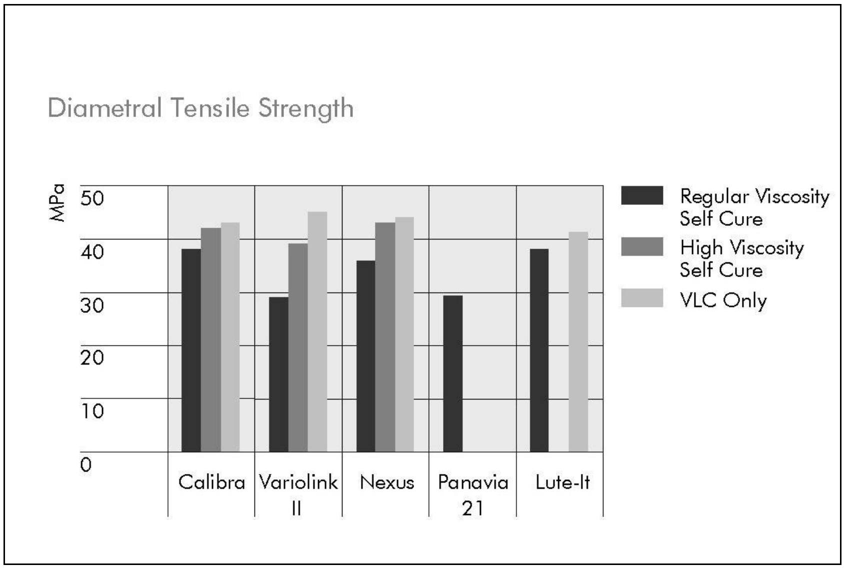



**Figure 11:** Diametral tensile strength of several self-cure resin cements

Film Thickness   Film thickness is an important criterion since relatively thin layers (25-200 µm) are required in order to ensure the accuracy of fit essential to luting cements.  Excess film thickness can lead to poorly-seated restorations. ***Calibra*** produces a film thickness of 11-19 µm, well within the limit stipulated in ISO Standard 9917 (25µm). (See Figure 12)

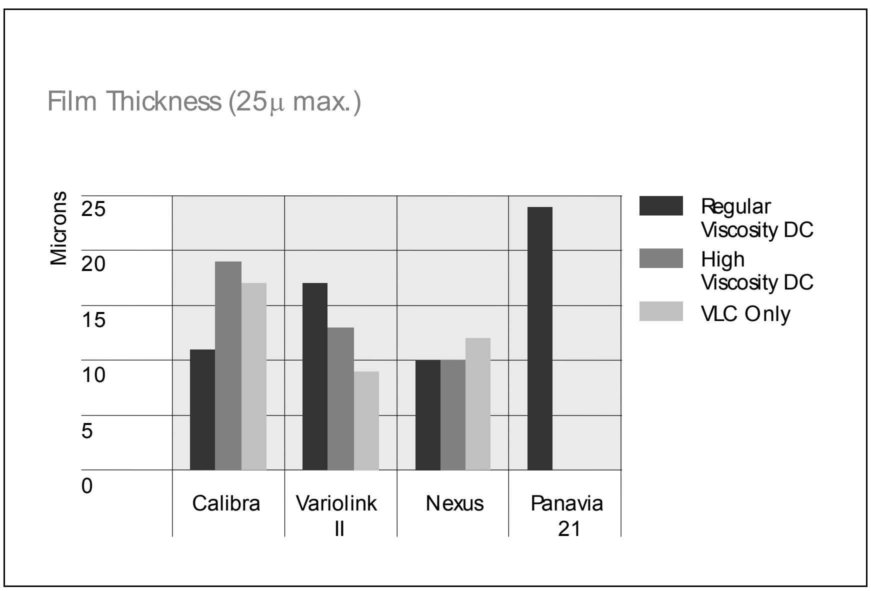



**Figure 12:** Film thickness for several regular-viscosity self-cure resin cements. The heavy bar at 25 microns represents the maximum film thickness according to ISO Standard 9917.

Depth of Cure The depth of cure is a measure of the sensitivity of the uncured cement to light, and particularly to the dental curing lights commonly used in dental practice. Although luting cements are generally used in very thin films, depth of cure takes on special importance when the cement is cured through the restoration as is the standard procedure for veneers and all-ceramic restorations.

Depth of cure is determined by filling an opaque cylinder with the material to be tested and then curing it from one end of the cylinder for a specified amount of time. Once the curing step is complete, the cured resin is removed from the cylinder and measured for its length from the point of light entry down to a depth corresponding to a given hardness.

The depth of cure for ***Calibra Esthetic Resin Cement*** is compared to that of other cements in Figure 13. Clearly, ***Calibra*** has a large depth of cure.

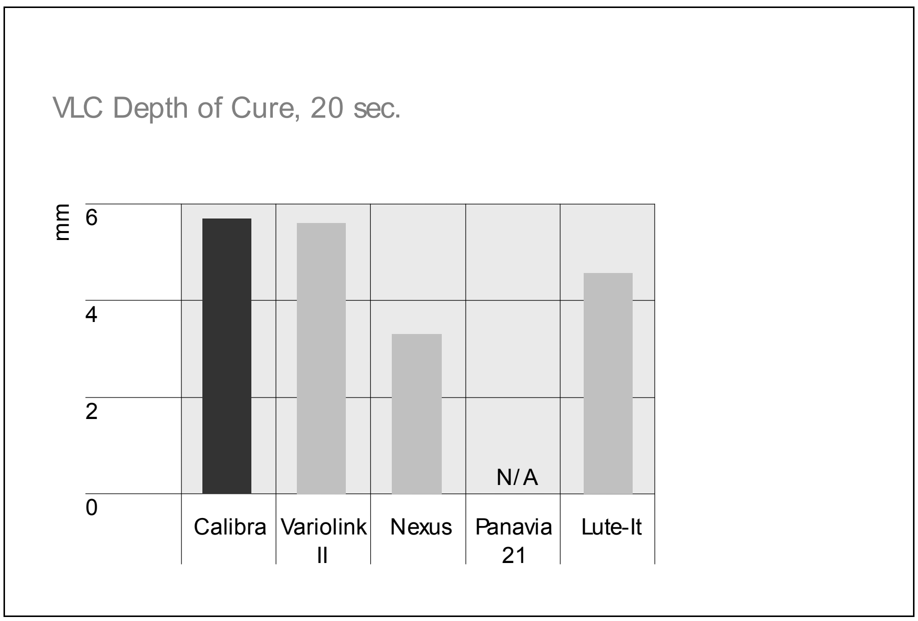



**Figure 13:** Depth of cure for several resin cements. Panavia 21 is not available in a light-cured version.

## Summary

***Calibra Esthetic Resin Cement*** brings together the strength and physical properties clinicians have come to expect from resin cements with the outstanding esthetic appearance that patients demand. Further, its ease of handling and versatility make it the luting system of choice for virtually all clinical applications.

## Directions for Use

Calibra Esthetic Resin Cement is a visible light cured, dual cured or self cured high strength resin cement compatible with dentin/enamel adhesive systems including Prime & Bond® NT and Prime & Bond NT Dual Cure Nano-Technology Universal Dental Adhesive to adhesively bond and lute indirect restorations to tooth structure.

The use of a dentin/enamel adhesive system is mandatory for use with CalibraEsthetic Resin Cement. Prime & Bond NT Adhesive or Prime & Bond NT Dual Cure Nano-Technology Universal Dental Adhesive is recommended for use with Calibra Esthetic Resin Cement. Other dentin/enamel adhesive systems may be used at the discretion and responsibility of the dental practitioner.

Caution: U.S. federal law restricts this device to sale by or on the order of a dentist.

**INDICATIONS**

1. Adhesive cementation of ceramic, porcelain, composite inlays/onlays, veneers and crowns.
2. Adhesive cementation of all metal crowns, bridges, inlays/onlays including precious, semi-precious and non-precious metals.
3. Adhesive cementation of PFM (porcelain fused to metal) crowns and bridges.
4. Adhesive cementation of prefabricated and cast posts.
5. Adhesive cementation of resin-bonded retainer bridges (Maryland bridges).

**CONTRAINDICATIONS**

- Calibra Esthetic Resin Cement is contraindicated for use as a base, liner, core build-up or filling material.
- Calibra Esthetic Resin Cement, Prime & Bond NT and Prime & Bond NT Dual Cure Nano-Technology Universal Dental Adhesive systems are contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.
- Prime & Bond NT and Prime & Bond NT Dual Cure Nano-Technology Universal Dental Adhesive systems are contraindicated for direct application to dental pulp tissue (direct pulp capping).
- Caulk 34% Tooth Conditioner1 is contraindicated for use on soft tissue including oral mucosa, skin, eyes and dental pulp tissue.

**WARNINGS**

- Calibra Esthetic Resin Cement, Prime & Bond NT and Prime & Bond NT Dual Cure Nano-Technology Universal Dental Adhesive contain polymerisable monomers which may cause skin sensitisation (allergic contact dermatitis) in susceptible individuals. Wash thoroughly with soap and water after contact. If skin sensitisation or other allergic reaction occurs, discontinue use.

- Calibra Esthetic Resin Cement, Prime & Bond NT and Prime & Bond NT Dual Cure Nano-Technology Universal Dental Adhesive contain methacrylates which may be irritating to the eyes. In case of contact with the eyes, rinse immediately with plenty of water and seek medical attention. Do not take internally.
- Flammable: Caulk Silane Coupler, Prime & Bond NT and Prime & Bond NT Dual Cure Nano-Technology Universal Dental Adhesive contain acetone. Keep away from sources of ignition. Do not breathe vapour.
- Caulk 34% Tooth Conditioner Gel[1] contains phosphoric acid which can cause burns of soft tissues. Avoid contact with oral soft tissues, eyes and skin. If accidental contact with the eyes occurs, immediately rinse with plenty of water and seek medical attention. Do not take internally.

**PRECAUTIONS**

- Eugenol containing materials should not be used in conjunction with this product because they may interfere with hardening and cause softening of the polymeric components of the material.
- Calibra Esthetic Resin Cement, Caulk Silane Coupler and Prime & Bond NT Dual Cure Nano-Technology Universal Dental Adhesive should be kept out of direct sunlight and stored in a well ventilated place at room temperature not exceeding 25¡C/77¡F.
- Caulk 34% Tooth Conditioner Gel[1], Caulk Silane Coupler and Calibra Resin Cement should extrude easily. DO NOT USE EXCESSIVE FORCE. Replace original cap tightly after each use to avoid evaporation. Discard syringe needle tip after use.
- The Calibra Esthetic Resin Cement, Caulk Silane Coupler and Prime & Bond NT Dual Cure Nano-Technology Universal Dental Adhesive system containers should be tightly closed immediately after use.

**ADVERSE REACTIONS**

Allergic contact dermatitis and other allergic reactions may occur in susceptible individuals.

**STEP BY STEP INSTRUCTIONS**

The following preparatory steps apply to cementation of all types of indirect restorations:

Following removal of the temporary restoration and any remaining temporary cement, clean enamel and dentin with a rubber cup and pumice or a non fluoride cleaning paste such as Nupro™ Prophylaxis Paste. Wash thoroughly with water spray and lightly air dry.

**Treatment of the Restoration**
Check the fit and esthetics of the restoration.

Technique Tip: Occlusal adjustment of inlays/onlays is best accomplished after final cementation.

Try-In Paste (Optional)
Dispense the appropriate shade of try-in paste from the syringe onto a clean mixing pad or glass slab. Load paste onto internal surfaces of the restoration and gently seat onto preparation. Clean excess with a cotton pellet and/or blunt explorer. The shade of the try-in paste is formulated to match the corresponding base shade as dispensed from the syringe, i.e., without mixed catalyst. Shades may be blended to achieve optimum esthetics. NOTE: The try-in paste will not polymerise, thus offers unlimited work time.

Once fit and esthetics are verified, thoroughly rinse try-in paste from restoration and preparation surfaces using water.

The internal surface of the restoration should be clean and dry prior to cementation. Organic debris accumulated during try-in may be removed by cleaning with ethanol or acetone followed by cleaning in water in an ultrasonic cleaner. The surfaces of porcelain or ceramic restorations may be further cleaned by using a liquid or gel phosphoric acid etchant followed by thorough rinsing and drying.

1. **Metal Restorations**
   Microetching (sandblasting) with 50μ alumina the internal surfaces of a metal restoration is recommended. Tin plating of high noble or gold metals is not required but will augment retention.

   Technique Tips For Maryland Bridges: The use of 180$^{O}$ wrap of wings, rest seats, parallelism and slots or grooves is necessary for appropriate retention. The metal wings of the Maryland

   Bridge should be perforated, electrolytically etched, laboratory chemically etched or mechanically sandblasted with 50μ alumina Chemical etching of the metal wings with Caulk 34% Tooth Conditioner Gel[1] (phosphoric acid) is not recommended. Etch should be verified under a microscope. For cementation, follow 2.0, Dual Cured directions.

2. **Ceramic/Porcelain/Composite Restorations**
   Microetching (sandblasting) with 50μ alumina or hydrofluoric acid chemical etching of the internal surfaces of a ceramic restoration is recommended. If the restoration has not been silane treated by the laboratory or if the

internal silanated surface has been disturbed during try-in, apply Caulk Silane Coupling Agent according to the following instructions.

Restoration Silanation

Treat inner surface of restoration as outlined above. Prior to applying the silane, clean the internal surface of the restoration with Caulk 34% Tooth Conditioner Gel (34% phosphoric acid). Apply for 30 seconds and rinse thoroughly with water for 20 seconds. Air-dry the internal surface of the restoration.

Attach supplied needle tip to end of the Caulk Silane Coupler syringe. Gently apply pressure to syringe plunger. DO NOT USE EXCESSIVE FORCE. Silane agent should express easily, one drop at a time. Directly apply the silane to the etched, clean internal surface of the restoration and allow to air dry.

NOTE:

Avoid application of the silane to the external surface of the restoration. Contact with the external surface will cause bonding of the cement to the external surface, complicating clean-up and necessitating removal of the glazed portion of the external surface of the restoration.

If silanated surface becomes contaminated, clean surface with alcohol or acetone, allow to air dry and repeat application as outlined above.

**Tooth Conditioning/Dentin Pretreatment**

1. Following restoration try-in, rinse preparation thoroughly with water spray and air dry.

2. Apply Caulk 34% Tooth Conditioner Gel[1].
   Attach disposable needle tip to end of syringe. Needle tip may be bent for easy access. Gently extrude Tooth Conditioner Gel1 on enamel margins. If a total etch technique is desired, continue to extrude Tooth Conditioner Gel[1] onto dentin surfaces. Condition enamel for at least 15 seconds and dentin for 15 seconds or less.

   Technique Tip: For full coverage crowns, condition remaining enamel only. Etching of full coverage dentin surfaces is not recommended to minimise the possibility of post-operative sensitivity.

3. Rinse and blot dry. Remove gel with aspirator tube and/or vigorous water spray and rinse conditioned areas thoroughly for at least 10 seconds. Blot dry conditioned areas with a moist cotton pellet.

Technique Tip: For best results, saturate a cotton pellet and remove excess water from the pellet by blotting it on a gauze pad before using the pellet to blot the tooth.

Blot drying provides the correct amount of "wetness" on the tooth surface by removing all excess moisture and avoiding desiccating the tooth surface. Do not rub the tooth surface when blot drying. Dentin should be blotted until there is no pooling of water, leaving a moist, glistening surface. Once the surfaces have been properly treated, they must be kept uncontaminated. If salivary contamination occurs, repeat procedure beginning at step 1.

**1.0 VENEER CEMENTATION-LIGHT CURED**

Before proceeding refer to above sections for Treatment of the Restoration and Tooth Conditioning/Dentin Pretreatment

Application of Prime & Bond NT Nano-Technology Light Cured Dental Adhesive

a. Dispense Prime & Bond NT adhesive directly onto a clean disposable brush provided, making sure that the bottle does not come into direct contact with the brush, or place 2-3 drops of Prime & Bond NT adhesive into a clean well. Replace cap promptly.

b. Using the disposable brush supplied, immediately apply generous amounts of Prime & Bond NT adhesive to thoroughly wet all the tooth surfaces. This surface should remain fully wet for 20 seconds and may necessitate additional applications of Prime & Bond NT adhesive.

c. Remove excess solvent by gently drying with clean, dry air from a dental syringe for at least 5 seconds. Surface should have a uniform glossy appearance. If not, repeat application and air dry.

d. Cure adhesive for 10 seconds2 using a curing light (i.e., ProLite™, Spectrum™).

e. Apply a single coat of adhesive to the internal bonding surface of the restoration. Immediately air dry for 5 seconds.

**Cementation Technique**

a. Dispense the desired shade of Calibra Esthetic Resin Cement base paste from the syringe directly onto the veneer. Protect cement from exposure to light.

b. Seat the loaded veneer in place. Remove excess from the gingival margin with a blunt instrument. Briefly (10 seconds or less) light cure the gingival portion only to tack restoration in place. Remove any excess from proximal and lingual margins.

Technique Tip: Placement of mylar strips between preparation and adjacent teeth prior to seating veneer aids in isolation and in excess cement clean up. After removing gingival excess and tacking veneer in place, remove interproximal excess cement by pulling mylar strip towards the facial, i.e., from tooth to restoration surface.

c. Light cure 20 seconds[2] each from the buccal, lingual, and interproximal aspects.

Following the light cure check and adjust occlusion as necessary. Proceed to Finishing and Polishing, section 4.0.

**2.0 CROWN/BRIDGE/INLAY/ONLAY CEMENTATION-DUAL CURED**

Before proceeding refer to above sections for Treatment of the Restoration and Tooth Conditioning/Dentin Pretreatment Application of Prime & Bond® NT™ Dual Cure Dental Adhesive System

a. Place 1-2 drops of Prime & Bond NT adhesive into a clean plastic mixing well. Replace cap promptly. Place an equal number of drops of Self-Cure Activator into the same mixing well. Replace cap promptly. Mix contents for 1-2 seconds with a clean, unused brush tip.

b. Using the disposable brush supplied, immediately apply mixed adhesive/activator to thoroughly wet all the tooth surfaces. These surfaces should remain fully wet for 20 seconds and may necessitate additional applications of mixed adhesive/activator.

c. Remove excess solvent by gently drying with clean, dry air from a dental syringe for at least 5 seconds. Surface should have a uniform glossy appearance. If not, repeat application and air dry.

d. Cure mixed adhesive/activator for 10 seconds2 using a curing light i.e., ProLite, Spectrum).

e. Apply a single coat of mixed adhesive/activator to the internal bonding surface of the restoration. Immediately air dry for 5 seconds.

**Cementation Technique**

a. Dispense the desired shade of Calibra Esthetic Resin Cement base paste from the syringe onto a clean mixing pad. Dispense an equal amount of the desired viscosity of catalyst paste (Regular or High Viscosity). Mix the cement for 20-30 seconds.

Technique Tip: **As with any dual cure resin cement system, the use of a dual cure adhesive system such as Prime & Bond NT Dual Cure**

**Dental Adhesive san shorten working time.** Calibra Esthetic Resin Cement base may be mixed with High Viscosity catalyst yielding a High Viscosity, "stay-put" thixotropic dual cured cement suitable for inlays, shallow onlays and veneers. Mixing Calibra Esthetic Resin Cement base with Regular Viscosity catalyst yields an easier flowing dual cured cement suitable for large, multi-surface and full coverage restorations with higher hydraulic seating pressure.

b. Apply a uniform layer of cement on the entire internal surface of the restoration. For inlays/onlays, it may be helpful to apply a thin layer of cement to the internal portions of the tooth preparation to avoid any porosity or voids. At room temperature, Calibra Esthetic Resin Cement, in either viscosity, offers a work time of at least (2 min. 30 sec.).

c. Seat the restoration with gradual pressure. A gentle rocking or vibratory motion may be helpful to insure optimal seating.

d. Remove gross excess from marginal areas. Use an instrument such as a blunted explorer, periodontal probe or a clean, dry brush tip. Restoration should not be moved or torqued during removal of gross excess cement. Special attention should be paid to interproximal areas using floss to remove excess cement.

   Technique Tip: A 10 second light "pre-cure" of excess cement at the margins will cause cement to "gel", allowing easy cleanup.

   Technique Tip: Apply moderate and consistent pressure to the restoration throughout the self cure set time of approximately 6 minutes from the beginning of mixing.

e. Once stabilised, light cure all marginal areas of the restoration for 20 seconds[2] from each direction - buccal, lingual and occlusal.

Following the self-cure set check and adjust occlusion as necessary. Proceed to Finishing and Polishing, section 4.0.

**3.0 ENDODONTIC POSTS**

Before proceeding refer to above sections for Treatment of the Restoration and Tooth Conditioning/Dentin Pretreatment

Application of Prime & Bond NT Dual Cure Dental Adhesive System

a. Place 1-2 drops of Prime & Bond NT adhesive into a clean plastic mixing well. Replace cap promptly. Place an equal number of drops of Self-Cure Activator into the same mixing well. Replace cap promptly. Mix contents for 1-2 seconds with a clean, unused brush tip provided.

b. Apply mixed adhesive/activator to post preparation with the brush provided, being sure to apply generous amounts to the preparation orifice. A paper point pre-wetted with the adhesive mixture may aid in bringing the adhesive mixture down to the deepest portion of the preparation. Maintain contact of adhesive/activator with tooth structure for at least 20 seconds.

c. Air dry treated post preparation with air syringe. Use of clean, dry paper points may aid in thorough removal of acetone in post space. Surface should have a uniform glossy appearance. If not, repeat application and air dry.

d. Apply a single coat of mixed adhesive/activator to the post with the same brush followed by gentle air drying for 5 seconds.

**Cementation Technique**

a. Dispense the desired shade of Calibra Esthetic Resin Cement base paste from the syringe onto a clean mixing pad. A light base shade e.g., Translucent will allow maximum light transmission. Dispense an equal amount of Regular Viscosity catalyst paste. Mix the cement for 20-30 seconds.

**Technique Tip: As with any dual cure resin cement system, the use of a dual cure adhesive system such as Prime & Bond NT Dual Cure Dental Adhesive san shorten working time.**

b. Spread mixed Calibra Esthetic Resin Cement components on surface of post and/or into the post preparation with a syringe tip, Lentulo Spiral or metal file.

c. Seat post immediately. Clean up excess with appropriate instruments. A 10 second light exposure "pre-cure" of excess cement at the margins will cause cement to "gel", allowing easy cleanup.

d. Stabilise post until cement sets. Apply moderate and consistent pressure to the restoration throughout the self-cure set time of approximately 6 minutes from the beginning of mixing. Light cure the cemented post for 20 seconds[2].

Proceed with core build-up and/or preparation.

## 4.0 FINISHING AND POLISHING

Removal of resin flash is best accomplished with the Enhance® Finishing System of points, cups and discs. The Enhance System will remove flash and finish restoration margins without removal of or trauma to the enamel.

Polish final restoration using Prisma®-Gloss™ Polishing Paste and Prisma-Gloss Extra Fine Polishing Paste with an Enhance foam cup. Apply each paste with the foam cup first dry for 20-30 seconds then wet with increasing amounts of water in a wet polishing technique.

U.S. Patent Nos. 4,514,342; 4,920,082; 5,304,586 and other patents pending.

[1] In Europe: DeTrey Conditioner 36
[2] Check curing light for minimum curing output of at least 300 mw/cm2

The European package contains DeTrey® Conditioner 36 and Prime & Bond NT.

## References

[1] **Phillips' Science of Dental Materials**, 10th ed., by Kenneth J. Anusavice (W.B. Saunders Co., Philadelphia, 1996).

[2] "Current Status of Luting Agents for Fixed Prostheses," **J. Pros. Dent., 81(2)**, by A.M. Diaz-Arnold, M.A. Vargas, and D.R. Haselton, pp135-141 (1999).

[3] "Dental Luting Agents: A Review of the Current Literature," **J. Pros. Dent., 80(3)**, by M.F. Land and B.J. Crispin, pp 280-301 (1998).

[4] **Elements of Dental Materials**, by R.W. Phillips and B.K. Moore, (W.B. Saunders Co., Philadelphia, 1994).

[5] "Contemporary Evaluation of Dental Cements," **Compendium, 20(3)**, by T.E. Donovan and G.C. Cho, pp197-220 (1999).

[6] "Novel Fracture Toughness Test Using a Notchless Triangular Prism (NTP) Specimen," **J. Biomedical Materials Research, 31**, by N.D. Ruse, T. Troczynski, M.I. MacEnttee, and D. Feduik (1996).