

### INDICATIONS

#### **What are the indications for use of Calibra Bio Cement?**

Calibra Bio Cement is indicated for the permanent cementation of:

- Metal and porcelain fused to metal crowns and bridges
- Gold inlays and onlays
- Cast or prefabricated metal posts
- High-strength ceramic crowns and bridges suitable for conventional cementation (e.g. zirconia, alumina, & lithium disilicate)

#### **What are the contraindications?**

Calibra Bio Cement is contraindicated for use as direct pulp-capping agent. In case of close proximity to the pulp, use accepted standard clinical procedures.

#### **Can Calibra Bio Cement be used on composite buildups?**

Clinicians should evaluate each case. Calibra Bio Cement has not been tested over composite core build-ups.

#### **Can Calibra Bio Cement be used on composite/fiber posts?**

No, not an indication

#### **Can Calibra Bio Cement be used on implants?**

Calibra Bio Cement can be used for crowns and bridges on abutments made of titanium or other metals used with high strength restorations (e.g. Zirconia) suitable for conventional cementation (but not on cementation of abutments). Calibra Bio Cement is radiopaque. It is extremely easy to clean up to avoid residual excess cement that could lead to complications. Its unique chemistry allows for excellent biocompatibility. We would not recommend to use the product where retrievability of the crown is the first or ultimate priority.

#### **Can I use for pre-fab SSC (Stainless Steel Crowns) (pedo)?**

Yes.

#### **Can I use for ortho brackets?**

No, not an indication

#### **Can I use for space maintainers (pedo application)?**

No, not an indication

#### **Can I use it for ceramic inlays/onlays?**

No, not an indication

#### **Can I use it for Maryland bridges?**

No, not an indication

#### **Is it ok to use with translucent esthetic crowns?**

Calibra Bio Cement is available in universal white shade (opaque white) only. This is due to its CA/Glass Ionomer composition and helps with easy cleanup of excess cement.

#### **Can I use with a bonding agent?**

No, bonding agents cannot be used with Calibra Bio Cement. Bonding agents are too hydrophilic and are not compatible with Calibra Bio Cement. Furthermore, there would be no link between bonding agent and cement as Calibra Bio Cement does not contain any resins. In general, do not use any pre-treatment agents, e.g. silanes, primers or bonding agents when cementing with Calibra Bio Cement. Use of any such pre-treatments will destroy the bond between cement and restoration.

#### **Can I use with my CEREC® machine?**

It depends on the material. Calibra Bio cement can be used with zirconia and high strength glass ceramics suitable for conventional cementation. CEREC machined restorations can be cemented with Calibra Bio Cement according to its indications (i.e. if material is suitable for conventional cementation). High strength glass ceramic restorations based on lithium silicate must be etched with HF acid before application according to manufacturer's instructions. No silane application is needed. For all other restorations, internal surfaces should be cleaned and dried prior to cementation with Calibra Bio Cement. It is recommended to micro etch the internal surfaces of metal and zirconia restoration by sandblasting with 50µ alumina. Do not use any pre-treatment agents, e.g. silanes, primers or bonding agents when cementing with Calibra Bio Cement. Use of any such pre-treatments will destroy the bond between cement and restoration.

#### **Where can I NOT use it?**

Calibra Bio Cement can be used according to its indications. For all other applications, Calibra Bio Cement cannot be used, e.g. for veneers, any low-strength ceramics, composite crowns and fiber/composite posts.

### CHEMISTRY AND PHYSICS

#### **What are the constituents of Calibra Bio Cement?**

The main constituents of the powder are Calcium aluminate (CA) and Glass ionomer (GI). In the liquid, the main constituent is water.

#### **“How does the material adhere to the prosthetic construction?”**

Calibra Bio Cement adheres to the prosthetic construction by wetting the surface and filling irregularities of the restoration surface through formation of calcium aluminate hydrate crystals. In general, the adhesion to the restoration is lower than for self-adhesive resin cements. It adheres via micro-mechanical retention. As with conventional cements, retention is the more relevant material property.

#### **How strong is the retention with Calibra Bio Cement?**

“An external crown retention study revealed the following results:

- 1) For gold crowns, Calibra Bio Cement shows retention at the same level as a self-adhesive resin cement and superior retention than a GI luting cement and a zinc phosphate cement.
- 2) For zirconia crowns, Calibra Bio Cement shows retention at the same level as a self-adhesive resin cement and the RMGI luting cement RelyX Luting Plus (3M).
- 3) For high strength lithium disilicate crowns, Calibra Bio Cement shows retention at the same level as a GI luting cement.”

#### **Is it dual cure? Self-cure?**

Self-cure

#### **What is the film thickness?**

About 20 microns

#### **Does it shrink?**

No shrinkage.

#### **What is the pH after fully hardening and how long will it last?**

For standard glass ionomer based products the pH value of the material is rising during the setting reaction from strongly acidic to slightly acidic or neutral. Calibra Bio Cement is different. Due to its calcium aluminate chemistry, the pH value after full hardening reaches the basic range. By the release of hydroxyl ions from the calcium aluminate part of the formulation, the acidity of the glass ionomer part is covered resulting in a pH value above 8 during the first 20 hours after application of the cement. How long the initially alkaline surface of the cement is maintained strongly depends on the influences within the oral environment, like salivation, consumed food & beverages, oral hygiene etc. This might be different for every patient and has not yet been fully investigated in vivo.

#### **Are there any other cements on market with the same chemistry and characteristics?**

Ceramir® Crown & Bridge (by Doxa)

#### **Is fluoride released?**

Yes

#### **What is the fluoride release?**

For the first 150 days, a cumulative fluoride release of about 200 µg/cm<sup>2</sup> has been measured.

### HANDLING

#### **How shall the tooth preparation be treated before using Calibra Bio Cement?**

- 1) Finish preparation or remove the temporary restoration and any remaining temporary cement.
- 2) If needed, clean the tooth using pumice or prophylaxis paste (with or without fluoride). Clean enamel and dentin with water spray and carefully dry with oil free air spray or cotton pellets. Do not desiccate the tooth structure. Keep moist.
- 3) Pulp Protection: In deep cavities/preparations, cover the dentin close to the pulp (less than 1mm) with a hard setting calcium hydroxide liner (Dycal® Liner).
- 4) Isolate the site with cotton rolls. Avoid contamination.

#### **Do I have to do anything special to the tooth?**

No. No etching, priming/bonding/conditioning to the tooth is needed. Do not use any pre-treatment agents, e.g. silanes, primers or bonding agents when cementing with Calibra Bio Cement. Use of any such pre-treatments will destroy the bond between cement and restoration.

### HANDLING (CONTINUED)

#### **Do I have to do anything special to the crown?**

“High strength glass ceramic restorations based on lithium disilicate must be etched with HF acid before application according to manufacturer’s instructions. No need for silane application. For all other restorations, internal surfaces should be cleaned and dried prior to cementation with Calibra Bio Cement. It is recommended to micro etch the internal surfaces of the restoration by sandblasting with 50 µ alumina. Do not use any pre-treatment agents, e.g. silanes, primers or bonding agents when cementing with Calibra Bio Cement. Use of any such pre-treatments will destroy the bond between cement and restoration.

#### **Which activator should be used?**

For Calibra Bio Cement no separate activator tool is required. The Calibra Bio Cement capsule is activated as follows:

- a) Hold the capsule firmly against a hard, flat surface with the plunger facing down.
- b) Push down firmly, forcing the plunger into the body of the capsule until it stops.

#### **Can you provide a list of triturator/mixer brands that work with the shape/size of your capsule?**

A list is available. Contact your DS sales representative or call customer service.

You can also visit the website [www.Calibracement.com](http://www.Calibracement.com). The following capsule mixers are recommended:

- 1) DS Capsule Mixer (Dentsply Sirona), just press the special “Calibra Bio Cement” button and you’re good!
- 2) ProMix Amalgamator (Dentsply Sirona) with high speed mode (rabbit mode, 4200 RPM)
- 3) Crescent Wig-L-Bug Mixer Model MSD (Dentsply Sirona) with 5000 RPM
- 4) Ultramat S (SDI, having a fixed speed of 4550 RPM)

Other compatible mixers: Capsule Mixer CM-II, RotoMix, Silamat S6, Optimix, and Renfert. After activation the capsule has to be placed immediately in a high-frequency oscillating or rotating capsule mixer. Calibra Bio Cement works well with varying mixers for 8 seconds at high speed (4000 - 5000 rpm). The dentist should make sure that the mixer is well maintained.

#### **Which applicator/extruder/applier should be used?**

Recommended applicators (DS Capsule Extruder 2, 3M/ESPE Applier, VOCO AC Applicator) have been tested to give the stated amount of cement. If you use any other brand of applicator/extruder it cannot be guaranteed that the extruded volume of cement will be within stated limits. This is especially true when the plunger of the applicator/extruder is shorter than for Calibra Bio Cement or Dentsply Sirona Extruder because then not all the cement can be pushed out of the Calibra Bio Cement capsules. The difference in plunger length should be obvious for the user.

#### **Can I use my other equipment (Activator/ Mixer/ Applicator/ Extruder/ Applier)?**

Recommended equipment and further examples are mentioned in the list above. In general, insufficient mixing time and/or frequency may result in an inhomogeneous paste. If the dentist observes a crumbly paste, it is recommended to check mixing time and mixing frequency of the used device. Do not use excessive force to extrude the mixed cement as capsule rupture may result.

#### **Can I use gluma before seating crown filled with Calibra Bio Cement?**

No, Calibra Bio Cement has not been tested in combination with gluma.

#### **Is it OK to clean the tooth surface with conditioner before using Calibra Bio Cement?**

Yes, as long as the surface is properly rinsed with water before cementation. However, conditioning is not necessary when using Calibra Bio Cement.

#### **Can you use Eugenol containing temporary cements for the temporary construction?**

Yes, it has been verified that using eugenol containing temporary cements does not affect Calibra Bio Cement properties.

#### **Will chlorhexidine on the tooth immediately prior to cementation interfere with the Calibra Bio Cement interaction?**

Calibra Bio Cement has not been tested in combination with chlorhexidine. We would recommend the use of alcohol.

#### **What is setting/working time?**

Working time is 2 minutes from end of mixing.

Setting time is 6-8 minutes from end of mixing.

Temperatures above 23°C/73°F will accelerate setting and reduce the working time available.

### HANDLING (CONTINUED)

#### **What are the steps/ process involved when used with lithium disilicate and zirconia?**

High strength glass ceramic restorations based on lithium disilicate must be etched with HF acid before application according to manufacturer's instructions. Do not apply silane before use of Calibra Bio. Make sure that the lithium disilicate material recommends the use of conventional cements.

Internal surfaces (Intaglio) for all other restorations should be cleaned and dried prior to cementation with Calibra Bio Cement. It is recommended to microetch the internal surfaces of the restoration by sandblasting with 50µ alumina. Do not use any pre-treatment agents, e.g. silanes, primers or bonding agents when cementing with Calibra Bio Cement. Use of any such pre-treatments will destroy the bond between cement and restoration.

#### **Can I use it with my Glass Ceramics?**

Calibra Bio Cement is indicated for permanent cementation of indirect restorations including high-strength ceramic crowns, and bridges suitable for conventional cementation. Please consult the manufacturer's Directions for Use to determine if the glass ceramic is indicated to be cemented with conventional cements.

#### **Can I use Ivoclean with Calibra Bio Cement?**

There is no need to use Ivoclean. Ivoclean is used to remove phosphates (protein) from saliva which may interfere with bonding to zirconia, primarily phosphate monomer containing primer or resin cement. For Calibra Bio cement, interference of phosphate with bonding agent is a non-issue. CalibraBio cement works well in the presence of phosphates. This is another step that could be eliminated. However, the use of Ivoclean will not negatively affect the way Calibra Bio cement works.

#### **Is Calibra Bio Cement easy to clean up?**

Calibra Bio Cement reaches a rubbery-like consistency approx. 2 minutes after mixing. Excess cement can be removed using an instrument such as a rubber tip, a scaler or an explorer. During the rubbery-like consistency or gel stage, Calibra Bio Cement is extremely easy to cleanup. Excess cement all comes off in one or few pieces. The overall cleanup protocol for Calibra Bio Cement is very user-friendly ensuring a convenient learning curve.

#### **Can I use dental floss when cleaning up?**

Yes, but only in apical direction, remove the floss in lateral direction. Push the floss through the contact, then pull it out interproximally.

#### **When can the patient eat?**

As a general rule when using conventional cementation, wait for at least one hour before loading the restoration.

#### **How moist should the prep be?**

Keep the tooth moist. Air-dry gently with oil-free air. Alternative method is to use a cotton roll to remove excess moisture.

#### **How many crowns can I get out of Capsule?**

One capsule per crown applies.

#### **Can crowns cemented with Calibra Bio Cement be cemented with resin cement later on?**

Yes, as long as all residues of cement are removed from the construction/restoration and the surface is properly reconditioned according to respective cements' Directions for Use.

#### **Why Calibra Bio Cement is not available in a syringe or as automix application?**

Calibra Bio Cement is based on a powder/liquid chemistry including calcium aluminate and glass ionomer components. A Calibra Bio cement capsule ensures proper mixing of both parts in the right amounts. This is not possible for syringe or automix applications. Only a capsule guarantees a fresh and proportioned mix each time for Calibra Bio cement.

Once clinicians understand the unique benefits of Calibra Bio Cement, the delivery system is a non-issue. Furthermore, there is no need to dispense and discard a small amount of material from the dual-barreled syringe each time before installing a mixing tip. Thus, the amount of wasted material is low.

#### **Can I get samples?**

Yes. Visit [www.calibracement.com](http://www.calibracement.com) or contact your DS sales representative.

## COMPLICATIONS

### **How can a prosthetic construction be removed when luted with Calibra Bio Cement?**

Use a crown removal procedure that is appropriate to the case. If unable to retrieve the crown intact, section it.

### **There doesn't seem to be enough cement in capsule, what's wrong?**

This might happen when using an applicator/extruder with a very short plunger, because then not all the cement can be pushed out of the capsules. The difference in plunger length should be obvious for the user. We heard reports that the GC applicator may not extrude well. However, we tested the GC Capsule Applicator 4 and it worked well with Calibra Bio Cement.

## PATIENT EXPERIENCE

### **Any post-op sensitivity?**

So far, there has been no report of post-op sensitivity. Resin-based cements are more prone to sensitivity. As with water-based cements, post-opt sensitivity is not a big challenge.

### **Any taste?**

None.

### **Is Calibra Bio Cement good for patients with allergies?**

Yes, as Calibra Bio Cement does not contain any resins, it is less prone to cause allergies.

## GENERAL

### **How does it compare cost-wise?**

Calibra Bio Cement is comparable to self-adhesive resin cements. Because of its simplicity of use, you will not need additional components such as primers, adhesives and cleaners which impacts cost as well as steps and efficiency. The intro kit offers the extruder and capsules at a significantly discounted price.

### **I am happy with my current cement. Why should I switch?**

No other cement is as close to the natural tooth structure as Calibra Bio Cement due to its unique bioceramic, bioactive chemistry. Calcium aluminate's unique characteristics create a seamless adaptation of the cement towards tooth structure and forms hydroxyapatite (HA) at the cement surface along the preparation margins when saliva from the oral environment is present. Both effects result in excellent marginal integrity of the restoration. It has been shown that Calibra Bio Cement minimizes microleakage. A three year study shows excellent marginal integrity, no marginal discolorations, no subject sensitivity, no secondary caries, and no loss of retention over time. It's an excellent choice to give your patients the best possible long-term results with the ease of use of a conventional cement and the retentive strength of a resin-based cement. Furthermore, Calibra Bio Cement had no reported sensitivity due to lack of any resins.

### **What is Hydroxyapatite (HA)?**

Hydroxyapatite (acronym: HA) is the primary mineral of human tooth enamel and dentin. It is a crystalline calcium phosphate. In the scientific community it is described with the chemical formula  $\text{Ca}_5(\text{PO}_4)_3(\text{OH})$ , or alternatively  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$  considering the two HA entities in the crystal structure.

When HA is formed in the oral environment, it helps protect marginal integrity to promote restoration longevity.

### **How much Hydroxyapatite (HA) is formed?**

Hydroxyapatite (HA) is formed as a layer where the cement is exposed to saliva in the oral environment along the preparation margins (cement-saliva interface). The thickness of the HA layer has not yet been clarified in vivo considering multiple external forces and influences. In vitro results reveal that HA formation of Calibra Bio Cement is able to fill gaps up to 110  $\mu\text{m}$  in height.

### **How soon/ How long is Hydroxyapatite(HA) formed?**

Hydroxyapatite (HA) starts to form in the initial curing state of the cement, when calcium and hydroxyl ions are released and get in contact with phosphate containing saliva. The growth of HA will stop at a certain point when no more calcium and hydroxyl ions are able to diffuse through the existing layer. In case the HA layer is removed or damaged calcium and hydroxyl ions would be available again and new HA is formed and precipitated. Therefore, the HA layer can be regarded as a self-repairing-layer.

### **What does Bioactive mean?**

Bioactive restorative and luting materials are interactive substances that help to trigger positive cellular response and/or repair of dental/oral tissues. Bioactive luting materials adhere to tooth structure without creating adverse reactions.

### GENERAL (CONTINUED)

#### **How is Calibra Bio Cement bioactive?**

For Calibra Bio Cement, one necessary condition to meet the definition for bioactivity is fulfilled by the apatite forming properties. A second, the adherence to tooth structure, is given for Calibra Bio Cement due to the glass ionomer (GI) part of the formulation. It is well known that GI restorative materials bond to tooth by ionic interactions.

#### **What does Bioceramic mean?**

Calibra Bio Cement falls into the bioceramic cement category due to the calcium aluminate part of its formulation. In general, Calcium aluminates (CA), when in the form of crystalline hydrates like Katoite, are defined as ceramics. A subgroup of ceramics are chemically-bonded ceramics, which are produced by chemical reactions at “low” temperatures, generally by combining a powder and a liquid. Ceramics used for the repair and reconstruction of diseased or damaged parts of the musculo-skeletal system, are termed bioceramics.

Calibra Bio Cement is a hybrid glass ionomer (CAIO) cement based on a combination of glass ionomer (GI) and calcium aluminate (CA) chemistry. It is applied by mixing a powder and a liquid resulting in both the GI setting reaction and the formation of crystalline Gibbsite and Katoite due to the calcium aluminate setting reaction. Therefore, Calibra Bio Cement can be classified into the group of chemically-bonded ceramics. Furthermore, Calibra Bio Cement is used for the repair of damaged parts of teeth. Consequently, Calibra Bio Cement can be termed a “bioceramic” luting cement.

#### **What does biocompatibility mean?**

Biocompatibility refers to the ability of a material to perform with an appropriate host response in a specific application.<sup>1</sup>

#### **Why do I need Calibra Bio Cement?**

Because other leading cements do not have the chemistry of Calibra Bio Cement. Other cements do not have calcium aluminate to produce HA on the surface in an oral environment. Therefore, they cannot close irregularities and voids and provide improved marginal integrity for your patients in the way that Calibra Bio Cement does.

#### **I have heard about Bioactive cements; is this the same as Activa and TheraCem?**

There are some similarities in terms of bioactivity but Calibra Bio Cement offers a unique chemistry that is beneficial for the long term success of the restoration. Only Calibra Bio Cement has calcium aluminate for seamless adaptation towards tooth and is proven to form HA in the oral environment. TheraCem is a self-adhesive luting cement containing standard resins (BisGMA, HEMA). Activa Cement is a typical Resin-Modified Glass Ionomer (RMGI) luting cement including urethane based resins. Some clinicians wrestle with the technique challenges inherent in resin cements. Calibra Bio Cement benefits from the advantages of a bioceramic cement's unique sealing abilities without the resins. It is easy to use and similar to conventional cements with excellent cleanup of excess cement. No HEMA, No Bis GMA, No BPA.

#### **Difference of calcium aluminates vs. calcium silicate?**

Calcium aluminates are a range of minerals obtained by heating calcium oxide (CaO) and aluminum oxide (Al<sub>2</sub>O<sub>3</sub>) together at high temperatures, i.e. the composition predominately consists of calcium and alumina. Calibra Bio Cement's formulation comprises approx. 50% of calcium aluminate.

Calcium silicate can be produced by reacting calcium oxide (CaO) and silica (SiO<sub>2</sub>) in various ratios. The best-known type is Portland Cement. For dental applications, calcium silicates are used as main ingredients for ProRoot MTA (Dentsply Sirona) and Biodentine (Septodont).