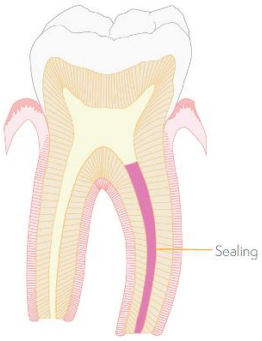
KometBioSeal Endodontic Sealer FAQ

CHOOSING A PRODUCT

What is KometBioSeal?	KometBioSeal is a premixed bioactive bioceramic endodontic sealer consisting of an extremely fine, inorganic powder of tricalcium/dicalcium silicate in an organic medium. The product is packaged ready-to-use. No mixing is required. KometBioSeal is designed to set in vivo in the presence of moisture from the surrounding tissues.
What are the indications for use?	Obturation and sealing of root canals. Read IFU prior to use. 
How does KometBioSeal set?	KometBioSeal is formulated with a water-free organic liquid. KometBioSeal sets in vivo. Setting begins in the presence of moisture from the apical tissues, dentinal tubules, or pulp.
Is KometBioSeal non-staining?	**YES.** KometBioSeal, contains tantalite as the radiopacifier, which does not cause staining. **Note:** Not all white MTA's are considered non-staining. White MTAs that contain bismuth oxide as the radiopacifier (e.g. ProRoot White MTA) will cause staining.
What makes KometBioSeal different from resin-based materials that contain some MTA?	Unlike inert, resin-based materials containing some MTA,... **KometBioSeal is:** • **Bioactivity;** KometBioSeal releases calcium and hydroxide ions from the MTA, promoting hydroxyapatite (HA) formation on the MTA surfaces to enhance sealing and support healing. • Formulated with pure tri/dicalcium silicate powder and a radiopacifier. • Dimensionally stable – unlike resin-based materials that shrink.

	• Biocompatible, non-cytotoxic. • More radiopaque. • Resin-free for maximum MTA concentration and maximum bioactivity. [*Resin-based materials containing only some MTA-type cement have not consistently shown biocompatibility in cell cultures[3,4], demonstrating a toxicity that may be attributed to incomplete resin curing.*] ***[3]Adıgüzel M, Ahmetoğlu F, Eldeniz AÜ, Tekin MG, Göğebakan B. Comparison of cytotoxic effects of calcium silicate-based materials on human pulp fibroblasts Mehmet. J Dent Res Dent Clin Dent Prospects. 2019;13(4):241-246.*** ***[4]Collado-González M, García-Bernal D, Oñate-Sánchez RE, et al. Cytotoxicity and bioactivity of various pulpotomy materials on stem cells from human exfoliated primary teeth. Int Endod J. 2017;50 Suppl 2:e19-e30.***
Is KometBioSeal the same as Portland cement?	**No:** While both Portland cement and MTA contain tricalcium silicate, they are not the same. Portland cement is: • **An impure** industrial grade construction product • **A coarse powde**r that sets slowly • **NOT** a medical device • **NOT** cleared by the FDA • **NOT** radiopaque • **NOT** a highly refined powder **Portland cement cannot meet the international dental standards,** including ISO 6876, ISO 9917-1 or ADA 57 requirements. KometBioSeal meets all dental quality standards and are manufactured in Houston, TX USA in an FDA-registered factory certified to ISO 13485.
How radiopaque is KometBioSeal?	KometBioSeal has a radiopacity of 6 mm Al equivalent. Increasing the radiopacity would lower the bioactive MTA content and potentially compromise the product's ability to set.

PRODUCT PRESENTATION

What Kit sizes are available and how many tips are included with each kit?	**Kit Size (gm)** / **Disposable Tips** 2.2 / 20	**Every KometBioSeal kit contains 20 Disposable Tips. These minimal waste tips ensure that product waste is minimized.*

APPLICATION, WORKING & SETTING TIME; RETREATMENT

Does KometBioSeal come with a dispensing tip?	Yes, KometBioSeal was designed to be the most efficient and economical bioceramic sealer in the market. KometBioSeal kit includes 20 Disposable Tips with the 2.2 kit. The

	Disposable Tips are designed to drastically reduce product waste compared to other dispensing tips.
What is the difference between KometBioSeal Disposable Tips and conventional tips on the market?	Our unique Disposable Tips combines the following features and benefits: • **Minimal waste barrel** reducing product waste by 40% compared to conventional tips. • **Minimal waste tips provided at no additional cost.** Every KometBioSeal kit includes 20 Disposable Tips with the 2.2 kit.
Can I use KometBioSeal without the Disposable Tip?	KometBioSeal may be dispensed without the Disposable Tip and used with the traditional cone buttering technique to coat the canal walls with an instrument and to coat the gutta percha points prior to its insertion.
Can I use any dispensing tip with KometBioSeal?	Yes, any dispensing tip designed with a luer-lock fitting maybe fitted to the KometBioSeal syringe, however we recommend the smallest tip used to be a 29-gauge tip, such as an Ultradent NaviTip™.
Can I use any brand of gutta percha with KometBioSeal?	Yes, however some brands of gutta percha points are waxier and the sealer may not appear to adhere to the point outside the root.
Do I need to completely dry the canals before applying KometBioSeal?	**No:** Moisture is required for setting of the sealer, supplied by the dentinal tubules and apical tissues. Clean & shape the canals and remove the smear layer. Remove pooled irrigants or excessive moisture from surrounding tissues with absorbent points.
What is the working time of KometBioSeal?	Working time at room temperature is 40 min ± 10 min. Setting begins in the presence of moisture provided by the surrounding tissues.
What is the final setting time of KometBioSeal?	KometBioSeal will set in vivo in 11 hrs ± 1 hr. The body fluids from the dentin tubules causes the product to set.
Will KometBioSeal shrink upon setting?	No, unlike some resin-based sealers, KometBioSeal is dimensionally stable and meets the ADA 57 standard: *ADA 57 std. <1% shrinkage & <0.1% expansion*
Is KometBioSeal resorbable in the case of material extrusion into the periapical area?	KometBioSeal is a biocompatible paste that will not result in a significant inflammatory response if a slight overfill occurs. Resorption in the periapical tissue may occur over years. However, it's important to NOT overfill the root canal forcing a large amount of sealer to be expressed beyond the apex of the root! When a large amount of material is overfilled into the mandibular canal (inferior alveolar canal), immediate surgical removal of the material should be considered, as with all root canal materials, according to state-of-the-art policy.

Can the KometBioSeal be removed for re-retreatment?	Yes. Use conventional instrumentation, including hand/rotary files and ultrasonic instrument tips, to remove KometBioSeal if it was placed with one or more gutta percha points.

CLEANUP AND STORAGE

What is the Shelf Life of KometBioSeal?	• The product has a 2-year shelf life. • Store at room temperature for optimal handling (do not refrigerate). • To prevent hardening of the KometBioSeal, immediately recap after each use. Store the syringe in the protective aluminum foil pouch provided.
Should I refrigerate the kit or its components?	**NO.** Store at room temperature for optimal handling (do not refrigerate). KometBioSeal should be stored at room temperature with the syringe cap tightly closed in its protective aluminum foil pouch container. **IF** accidently refrigerated or if stored in a cool environment, place KometBioSeal at room temperature for 35 minutes for optimal handling. A faster option would be to keep the syringe in your pocket for 10 minutes before use.
How do I clean instruments that have contacted KometBioSeal?	Warm water may be used to clean instruments if the material has not hardened. If hardened clean with vinegar or other mild acid. **NOTE:** KometBioSeal is a non-sterile product. Follow your established cleaning and sterilization procures for instruments as appropriate.