

Harvard BioCal® - RootSeal

Bioactive resin-modified MTA Root Canal Sealer

Harvard BioCal® - RootSeal is a bioactive two-component paste/ paste root canal sealer based on acrylic resin modified MTA. It shows a high pH of 12. Harvard BioCal® - RootSeal can create apatite and bonds to the root canal walls. Sealing of the root canal is excellent due to virtual no shrinkage of Harvard BioCal® - RootSeal.

Harvard BioCal® - RootSeal shows an excellent radiopacity. In case of revisions, Harvard BioCal® - RootSeal can be removed easily.

Indications:

Permanent root canal filling of the secondary dentition in combination with gutta percha points.

Contraindications

In cases where the root canal has been treated with eugenol containing products, do not use Harvard BioCal® - RootSeal.

Isolation

Rubber dam is the recommended method of isolation.

1. Preparation of the Root Canal

Prepare and clean the root canal (e.g. with Harvard Glide & Clean). Dry the canal using paper points.

Do not use any lubricant or irrigants that are not specifically designed for

2. Application of Harvard BioCal® - RootSeal

2.1. Preparing the MINIMIX-Syringe and the Harvard EndoDirect syringe

Take the MINIMIX-syringe from the resealable aluminum bag. Store the aluminum bag!

Remove the cap of the MINIMIX-syringe and discard it (do not use it again!). It is replaced by the supplied mixing cannula. Turn the cannula 90° until it locks in position.

Discard the first 2-3 mm of the extruded material. This must be done for each new mix. Store the used MINIMIX-syringe with fixed used mixing cannula.

Remove the plunger of the MINIMIX-syringe and put the MINIMIXsyringe back into the aluminum bag.

Check the Harvard EndoDirect syringe for tightness of the dispensing tip.

Use only the fitted flexible endo tip in combination with the Harvard EndoDirect syringe!

Mark the working length with the silicone stop. Remove the plunger from the syringe.

2.2. Application

Fill the required amount of mixed Harvard BioCal® - RootSeal from the MINIMIX syringe into the Harvard EndoDirect syringe.

Protect the filled EndoDirect syringe from direct light!

Fix the plunger and inject passively Harvard BioCal® - RootSeal into the root canal to the working length. Filling should occur from bottom upwards. Apply the gutta percha master point into the root canal to the working length and condense the root canal filling with additional gutta percha points.

Using a heating device to cut the remaining excess of the gutta percha at the coronal part. And condense the gutta percha for a better sealing with a

As an alternative place the mixed Harvard BioCal® - RootSeal on a mixing pad and fill the root canal using a lentulo.

Harvard BioCal® - RootSeal has a working time of 10 minutes (at 23°C/74°F).

Light cure Harvard BioCal® - RootSeal at the orifice for 40 seconds with a dental curing unit. Light curing will create a thin layer of superficially hardened surface.

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Instructions for Use **EN**

Full polymerization in the root canal will occur within 1 hour.

After light curing the surface of the root canal filling seal the cavity with a temporary filling material or proceed with core build-up or filling.

3. Additional Notes

- Contact of resin pastes with skin should be avoided, especially by anyone having known resin allergies. Do not use for patients with allergic reactions against methacrylates.
- Neither store the material in proximity of eugenol containing products, nor let the material allow to come into contact with materials containing eugenol. Eugenol impairs the hardening of the material.

Storage

Store at 2 – 8 °C (36 – 46 °F) in the original seal-pack. After opening of the seal-pack store the material protected from light and moisture at room temperature (19 - 25 ° C / 66 - 77 °F). Use up within 6 months and before the end of expiry date. Do not use after expiry date.

The Harvard EndoDirect syringe is for single use only.

Warnings:

- Harvard BioCal® RootSeal contains polymerisable methacrylate monomers. Unpolymerized materials may have an irritating effect and may lead to a sensitizing reaction against methacrylates.
- Do not use with patients with allergic reactions against acrylates.
- Avoid contact with skin, mucous membrane and eyes.
- In case of contact with eyes, rinse with copious amounts of water and consult a physician immediately. In case of skin contact wash immediately with water.
- Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the material. Neither store the material in proximity of eugenol containing products, nor let the material allow coming into contact with materials containing eugenol.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.

Warranty

Harvard Dental International GmbH warrants this product will be free from defects in material and manufacture. Harvard Dental International GmbH makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and Harvard Dental International GmbH's sole obligation shall be repair or replacement of the Harvard Dental International GmbH product.

Limitation of Liability

Except where prohibited by law, Harvard Dental International GmbH will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

For dental use only!

Store product out of reach of children!

Keep the instructions for use for the duration of the application.

Order-No.	Article
7081552	2.5 ml Minimx-syringe Harvard BioCal® - RootSeal,
	10 EndoDirect syringes with flexible endo tip,
	10 mixing tips Harvard Mini 4:1 / 10:1 S-Brown,
7081553	2.5 ml Minimx-syringe Harvard BioCal® - RootSeal,
	5 mixing tips Harvard Mini 4:1 / 10:1 S-Brown,
	5 mixing tips Harvard Mini 4:1 / 10:1 O-Brown,
	5 intra tips long, mixing pad
7093050	Harvard Mini 4:1 / 10:1 S-Brown
	refill bag with 50 mixing tips
7091100	Harvard Mini 4:1 / 10:1 O-Brown
	refill bag with 50 mixing tips

