

VARYFLEX[®]

BIOC

BIOCERAMIC SEALER

ENGLISH

DEFINITION

Ready to use endodontic bioceramic obturator cement.

INDICATIONS

1. Sealing the root canal of permanent teeth;
2. Internal reabsorption treatment.

INTENDED PUBLIC

Patients with closed apex permanent teeth diagnosed with pulp or periapical disease.

INTENDED USERS

VARYFLEX BIOC should only be used by dental surgeons trained to perform endodontic procedures.

INTENDED ENVIRONMENTS

Dental practices.

CONTRAINDICATIONS

- Do not use the product after the expiration date;
- If the packaging is damaged, the product should not be used;
- Do not use in patients who have previously reported sensitivity to any of the formula's components.

COMPOSITION

Calcium Silicates, calcium aluminate, calcium oxide, zirconium oxide, iron oxide, silicon dioxide and dispersing agent.

TECHNICAL INFORMATION

- Biocompatible product ready for use;
- Setting time: 30-240 minutes after insertion into the canal, according to ISO 6876;
- ① *Important: Dry with paper cones, but without excessively drying the canal; The moisture from the dentin tubules will initiate the material's setting reaction;*
- High alkalinity;
- High radiopacity;
- Does not suffer setting contraction;
- It can be used, in addition to conventional techniques, in single-cone techniques and thermoplastic filling.

WARNINGS

- Use absolute isolation in all indications;
- Do not use VARYFLEX BIOC to fill the canal without the gutta percha cones;
- The product is sensitive to moisture, so properly close the packaging with proper pressure to prevent dryness;
- Never store it in a refrigerator;
- Dry the canal with paper cones, but without excessively drying the canal; the moisture from the dentin tubules will initiate the material's setting reaction;
- Use the product only after controlling the infection, because at this stage the material's setting reaction does not occur due to the acidic pH in the area;
- Avoid causing excessive overflow of the product to the periapical region;
- Do not reuse the applicator tips;
- Clean and disinfect the syringe in subsequent uses to avoid cross-contamination.

PRECAUTIONS

- Wear safety goggles, mask and gloves when handling the product. In case of contact with eyes or skin, wash with water;
- Prior to use, disinfect the applicator tip. After use, the tip should be discarded;
- Clean and disinfect the syringe after each subsequent use;
- Return the properly closed syringe, along with the silica sachet, to the packaging, which must be properly closed and stored in accordance with the topic "STORAGE";
- On subsequent use, check that the silica sachet inside the envelope remains blue in color;
- The safety and efficacy of use in pregnant or breastfeeding women, children, or adolescents have not been established;
- Keep out of the reach of children.

USE TECHNIQUE

Use of Applicator Tips

1. We recommend using a disposable plastic cover on the syringe to avoid cross-contamination;
2. Confirm the material exits from the syringe before direct application to the channel;
3. Position the tip and syringe assembly properly into the canal and depress the plunger lightly to prevent excessive output of the product;

- Before closing the syringe, retract the plunger to stop the outflow;
- Clean any excess material on the tip of the syringe and close with appropriate pressure after use to prevent contact with moisture, which causes the product to dry;
- Clean and disinfect the syringe in subsequent uses to avoid cross-contamination; in case of contamination with saliva or blood, discard it.

A. SEALING THE ROOT CANAL OF PERMANENT TEETH;

Traditional technique - Lateral compression

- Anesthetize, install absolute isolation and then perform the biomechanical preparation of the canal;
- Remove the sealing tip and attach the applicator tip on the syringe;
- Dry the canal only with absorbent paper cones without causing excessive dryness;
- Apply VARYFLEX BIOC in the apical third of the canal directly with the syringe;
- Insert the gutta percha cone in the canal according to the last file used covered with VARYFLEX BIOC;
- X-ray for checking the correct filling of the canal;
- Cut the cone at the desired height with heated instruments followed by vertical compression;
- Remove, with water, excessive material from the canal walls, perform crown sealing and restoration.

Important:

- VARYFLEX BIOC does not suffer setting contraction;
- VARYFLEX BIOC can be used in conventional, single cone and thermoplastic obturation techniques;
- Use conventional gutta removal techniques.

Single-cone technique

- Anesthetize, install absolute isolation and then perform the biomechanical preparation of the canal;
- Remove the sealing tip and attach the applicator tip on the syringe;
- Dry the canal only with absorbent paper cones without causing excessive dryness;
- Apply VARYFLEX BIOC in the apical third of the canal directly with the syringe;
- Insert the gutta percha cone;
- X-ray for checking the correct filling of the canal;
- Cut the cone at the desired height with heated instruments followed by vertical compression;
- Remove excessive material from the canal walls with suitable irrigating solutions for this purpose, perform crown sealing and restoration.

B. INTERNAL REABSORPTION TREATMENT

- Anesthetize and install absolute isolation;
- Remove granulation tissue from reabsorption area with sharp curettes;
- Neutralize the area with calcium hydroxide paste or BIO-C TEMP;
- Remove the calcium hydroxide or BIO-C TEMP in the next session;
- Dry the canal only with absorbent paper cones without causing excessive dryness;
- Insert VARYFLEX BIOC with the applicator tip across the canal, prioritizing the reabsorption area;
- Insert the accessory gutta percha cones according to the lateral compression technique;
- Cut the cones at the upper part of the reabsorption with heated instruments. Perform vertical compression for better disposal of the sealer in the reabsorption area;
- X-ray for checking the correct filling of the reabsorption and canal area;
- Fill the remaining of the canal with gutta percha;
- Perform crown sealing with glass ionomer or other material of your preference and restore the tooth;
- X-ray and follow up for at least two years.

Filling removal

- Use conventional gutta removal techniques.

STORAGE

- Keep the product in a dry and ventilated place between 15 and 30°C and with relative humidity below 60%;
- Do not store it in a refrigerator.













DISPOSAL METHOD

The product must be disposed of in accordance with local regulations.

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Symbology

RX ONLY

	Single use accessories.		Non sterile.		Use-by date.
	Consult instructions for use.		Reference number.		Batch number.
	Keep away from sunlight.		Date of manufacture.		Temperature limit.
	Keep dry.		Manufactured by.		Medical devices

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ATTENTION: This product must be used according to the instructions described in this manual. The manufacturer is not responsible for failure or damage caused by incorrect handling or use.