



# **Temporary Root Canal Filling Material**

Premixed Calcium Hydroxide Paste with Barium Sulfate

### General Information

VioPaste® is a highly versatile temporary root canal filling material composed of Calcium Hydroxide and Barium Sulfate. These principal components with Hydroxyapatite provide superior biocompatibility while stimulating apical calcification for a successful apexification treatment. VioPaste® has a dough-like consistency for a constant flow and easy application into the canal.

### Composition

· Calcium Hydroxide, Barium Sulfate, Hydroxyapatite, others

### Indication

- · Apexification treatment
- · Root canal filling for the removal of exudates
- Temporary root canal filling for prevention of pulp exposure and infection
- · Precision canal tapering

### **Precautionary Information**

- 1. Check the expiration date and appearance condition of product and package.
- 2. Observe the instruction for use after being well acquainted with the instruction for use.
- 3. Do not use the product after the expiry date.

# **Application**

- 1. Check the prepared canal for inhibition of exudation.
- Begin filling the canal from the apex. Withdraw the tip slowly from the canal still running at uniform speed. Backfill the canal space to canal orifice only.
- Caution should be taken not to overfill the canal beyond the apical foramen.It may cause pain or discomfort for the patient, and will have to be properly removed.
- 4. Discard the application tip after use and remount the protective cap.

#### Caution

- VioPaste® is designed for sale and use by licensed dental care professionals only.
   It is not designed for sale nor is it suitable for use by non-dental care professionals.
- 2. If VioPaste® causes an allergic reaction or oversensitivity, discontinue its use immediately.
- 3. Avoid contact of VioPaste® with eyes, mucosal membrane, skin and clothing.
- If VioPaste® comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.

Conformity with	Comunaute Europeenne
Temperature limit	150
Keep away from sunlight	类
Keep dry	#
Authorized representative in the European Community	EC REP
Federal law prohibits dispensing without a prescription	Rx Only

## IFU#164337(R 04/23)

# Manufacturer



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# **EC REP EU** representative

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- 5. Use a rubber dam to protect the throat.
- 6. DO NOT use VioPaste® after the indicated expiration date on the syringe.
- 7. When using dental root canal filling materials, be careful not to extrude the filling material out of the root canal.
- If the root canal filling material were extruded excessively out of the root canal beyond the apical due to
  overfilling, extreme pain, delayed recovery, and sensory abnormalities may occur depending on the amount
  of extrusion and surrounding anatomical structures.

## Storage & Use

- 1. Store VioPaste® at a temperature between 15 25°C.
- 2. Ambient temperatures routinely higher than 25°C/77°F may reduce shelf life.
- 3. Shelf life at room temperature is 36 months.
- 4. See outer package for expiration date.

## Warranty

Spident® warrants this product will be free from defects in material and manufacture. Spident®, MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is re sponsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and Spident®'s sole obligation shall be repair or replacement of the Spident®'s product.

# **Limitation of Liability**

Except where prohibited by law, Spident® 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.

### **Customer Information**

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Caution: U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

### Disposal

It should be handled according to local laws and regulations.

Batch code	LOT
Date of manufacture	س
Used-by date	Σ
Caution	$\triangle$
Manufacturer	w
Medical Device	MD