

## DIRECTIONS FOR USE

**DENTSPLY**  
TULSA DENTAL  
SPECIALTIES

# ThermaSeal® Plus ROOT CANAL SEALER

# ThermaSeal® Plus RIBBON™ ROOT CANAL SEALER MIXING SYRINGE

Manufactured For:  
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Made in Germany



ThermaSeal Plus Root Canal Sealer is a two-component paste root canal sealer based on epoxy-amine resin, offering the following features:

- Long-term sealing properties
- Outstanding dimensional stability
- Self-adhesive properties
- Very high radiopacity

ThermaSeal Plus Root Canal Sealer comes in the following deliveries:

- as ThermaSeal Plus Root Canal Sealer in tubes for manual mixing of pastes A and B
- as ThermaSeal Plus Ribbon™ Mixing Syringe offering a more precise, convenient and faster procedure.

## COMPOSITION

### ThermaSeal Plus Paste A

Bisphenol-A epoxy resin  
Bisphenol-F epoxy resin  
Calcium tungstate  
Zirconium oxide  
Silica  
Iron oxide pigments

### ThermaSeal Plus Paste B

Dibenzyl/diamine  
Aminoadamantane  
Tricyclodecane-diamine  
Calcium tungstate  
Zirconium oxide  
Silica  
Silicone oil

## INDICATIONS FOR USE

Permanent obturation of root canals of teeth of the secondary dentition in combination with root canal points.

## CONTRAINDICATIONS

Use with patients who have a history of severe allergic reaction to epoxy resins or amines or any of the other components.

## WARNINGS

The material contains epoxy resins and amines which may be irritating to skin, eyes and oral mucosa. The material may also cause allergic contact dermatitis in susceptible persons.

- Avoid eye contact to prevent irritation and possible corneal damage. In case of contact with eyes rinse immediately with plenty of water and seek medical attention.
- Avoid skin contact to prevent irritation and possible allergic response. In case of contact, reddish rashes may be seen on the skin. If contact with skin occurs, immediately remove material with cotton and alcohol and wash thoroughly with soap and water. In case of skin sensitization or rash, discontinue use and seek medical attention.
- Avoid contact with oral soft tissues/mucosa to prevent inflammation. If accidental contact occurs, immediately remove material from the tissues. Flush mucosa with plenty of water after the restoration is completed and expectorate/evacuate the water. If inflammation of mucosa persists, seek medical attention.
- Prevent ingestion. If accidental swallowing occurs, have patient drink plenty of water. If nausea or illness develops, seek medical attention.
- Do not place too much sealer to prevent overfilling of the root canal and damage of periapical tissue.

## PRECAUTIONS

Any use of this product inconsistent with these Instructions For Use is at the discretion and sole responsibility of the dental practitioner.

- If refrigerated, allow material to reach room temperature prior to use.
- Use protective measures for the dental team and patients such as glasses and rubber dam in accordance with local best practice.
- Contact with saliva, blood and sulcus fluid during application may cause failure of the root canal filling. Use adequate isolation such as a rubber dam.
- ThermaSeal Plus Ribbon root canal sealer missing tips are intended for single use only. Do not reuse in order to prevent cross-contamination or malfunction.

## ADVERSE REACTIONS

- Eye contact: Irritation and possible corneal damage.
- Skin contact: Irritation or possible allergic response. Reddish rashes may be seen on the skin.
- Contact with mucous membranes: Inflammation (See Warnings).

## STEP-BY-STEP INSTRUCTIONS

### Storage

Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product.

- Store at temperature between 10°C and 24°C (50°F and 75°F). Use the product at room temperature.
- Do not freeze.
- Do not use after expiration date.

### Preparation of the Root Canal

Prior to application of ThermaSeal Plus Root Canal Sealer, prepare, clean, and dry the root canals to be filled using state-of-the-art endodontic techniques.

### Dosage and Mixing

#### Using ThermaSeal Plus Root Canal Sealer in tubes:

Paste B may slightly separate. It has been shown that this process does not negatively affect the performance of the mixed product.

1. Using a metal spatula, mix equal volume units (1:1) of paste A and paste B of ThermaSeal Plus Root Canal Sealer on a glass slab or the mixing pad supplied with the package. Mix to a homogeneous consistency.
2. Tightly close tubes after use.
3. Do not exchange caps of tubes. The colored cap belongs to the colored tube; the white cap belongs to the white tube.

#### Using ThermaSeal Plus Ribbon Mixing Syringe

The syringe filling volumes of pastes A and B vary slightly. To ensure appropriate mixing, bleed the syringe prior to the first use.

1. Remove the cap by turning it 90° counter-clockwise and pulling it.
2. Attach the mixing tip to the syringe, aligning the notch.
3. Turn the tip 90° clockwise and secure the mixing tip in place.
4. Rotate and adjust the tip in angle in order to meet treatment requirements.

5. Use DisposaShield® protective barrier when cross-contamination cannot be avoided.
6. Carefully apply steady pressure onto the plunger. The two pastes are automatically mixed in equal volume units.
7. After having finished remove mixing tip by turning it 90° counter-clockwise and pulling it off (together with protective barrier if any).
8. Replace the cap on the syringe head, aligning the notch, then turn it 90° clockwise.

## APPLICATION

### Overfilling

Damage of periapical tissue.

1. Do not place too much sealer to prevent overfilling of the root canal. For condensation and warm gutta-percha obturation techniques apply only a light coating of sealer onto the canal walls.
2. If overfilling occurs the material is usually tolerated very well by the surrounding tissue. If however material is pressed into the mandibular canal, immediately apply state-of-care measures.

### Condensation and Warm Gutta-Percha Techniques

1. As a standard technique, the material is used in combination with gutta-percha or other root canal points.
2. For these filling techniques where most of the canal is obturated by endodontic point material, apply a light coating of sealer with paper point, gutta-percha point or file onto the canal walls to the working length.

### Master-Point-Technique

1. Select a gutta-percha point (or alternatively a paper point or a reamer) of the size of the last instrument used during apical preparation.
2. Wet the canal walls with the material through a pumping or simultaneously rotating movement in a counter-clockwise direction of the point/reamer. Alternatively, apply the material onto the tip of a Lentulo spiral.
3. Advance the Lentulo spiral slowly to the apex running at very low speed. Avoid the formation of air bubbles in the material and overfilling the canal.
4. Withdraw Lentulo very slowly still running at low speed.
5. Dip disinfected and dry master point into the material and insert it into the canal with a slow pumping motion.

### Working Time

The working time is at minimum 4 hours at 23 °C<sup>1</sup>. (73° F)

### Setting Time

The setting time is at minimum 24 hours at 37 °C<sup>2</sup>. (98.6° F)

## CLEANING OF INSTRUMENTS

Spatulas, mixing slabs and instruments should be cleaned with alcohol or acetone immediately after use.

## Removal of Root Canal Filling

If the material is used in combination with gutta-percha points, root canal fillings can best be removed using thermo-mechanical techniques.

## LOT NUMBER (LOT) AND EXPIRATION DATE (EXP)

1. Do not use after expiration date. ISO standard is used: "YYYY/MM"
  - Reorder Number
  - Lot Number
  - Expiration Date

<sup>1</sup>Internal test method.

<sup>2</sup>measured according to ISO 6876:2001 (E).

## STERILITY SECTION.

Product is non-sterile.