

ThermaSeal® Plus Ribbon®

Root Canal Sealer

CAUTION: For dental use only.
In the USA: Rx only.

1 Product description

ThermaSeal® Plus root canal sealer and **Ribbon®** root canal sealer are based on epoxy-amine resin, offering the following features:

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

1.1 Indications

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

1.2 Contraindications

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

1.3 Delivery forms

- ThermaSeal® Plus in tubes for manual mixing of paste A and paste B.
- Ribbon® mixing syringe offering a more precise, convenient and faster procedure.

1.4 Composition

Paste A (amber color)

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

Paste B (white color)

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

Bisphenol-A epoxy resin.



The Bisphenol-A epoxy resin contained in ThermaSeal® Plus/Ribbon® is according to IUPAC nomenclature 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis-oxirane (CAS No. 1675-54-3) and must not be taken for the Bisphenol-A (BPA) present in many consumer and some dental products and what has raised concerns about possible adverse health effects.

2 Safety notes

Be aware of the following general safety notes and the special safety notes in other chapters of these Directions for Use.



Safety alert symbol.

- This is the safety alert symbol. It is used to alert you to potential personal injury hazards.
- Obey all safety messages that follow this symbol to avoid possible injury.

2.1 Warnings

The material contains epoxy resins and amines which may be irritating to skin, eyes and oral mucosa and may 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, 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, remove material from the tissues. Flush mucosa with plenty of water 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.

2.2 Precautions

This product is intended to be used only as specifically outlined in these Directions for Use.

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

- 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 rubber dam.
- The syringes cannot be reprocessed. To prevent the syringes from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringes are handled with clean/disinfected gloves. Discard syringes if contaminated.
- As additional precautionary measure, the syringe may be protected from gross contamination but not from all contamination by applying the single use Disposa-Shield® protective barrier¹.
- Ribbon® root canal sealer mixing tips and Disposa-Shield® protective barrier are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross-contamination or malfunction.
- Interactions:
 - If refrigerated, allow material to reach room temperature prior to use.

2.3 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).

2.4 Storage conditions

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

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

3 Step-by-step instructions

3.1 Preparation

1. Prior to the application of the material prepare, clean, and dry the root canals to be filled using state-of-the-art endodontic techniques.

3.2 Dosage and mixing

3.2.1 ThermaSeal® Plus root canal sealer (tubes)



Appropriate paste condition.

For Paste B slight separation may occur. This condition does not negatively affect the setting time of the mixed product. If the dispensed material is solely of clear color, discard the dispensed material, to ensure convenient handling of the mixed paste.

1. Using a metal spatula², mix equal volume units (1:1) of paste A (amber color) and paste B (white color) 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 white cap belongs to paste A; the colored cap belongs to paste B.

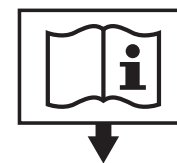
3.2.2 Ribbon® root canal sealer (mixing syringe)



Appropriate mixing ratios.

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

**Dentsply
Sirona**



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Electronic directions for use available online

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¹ Disposa-Shield® Infection Control Barrier for low speed, long handpiece, Reorder A88006.

² Mixing ratio by weight is 1 g of paste A to 1.18 g of paste B.

The Ribbon® syringe cannot be reprocessed. To prevent the Ribbon® syringe from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringe is handled with clean/disinfected gloves.

1. Remove the cap by turning it 90° counter-clockwise and pulling it.
2. Attach the mixing tip³ 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 Disposa-Shield® 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.

3.3 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.

Clogging.

Separation of mixing tip from syringe.

1. Do not allow material to dry inside.
2. Do not reuse mixing tip.
3. Always make sure mixing tip is properly connected to syringe before application. The material should extrude easily.

3.3.1 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 a paper point or file onto the canal walls to the working length and/or apply a light coating of sealer onto the surface(s) of the root canal filling point(s).
3. Insert root canal filling point(s) into the canal according to standard procedure.

3.3.2 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 of 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.

3.3.3 Working and setting time

- Working time is 4 hours at 23 °C⁴.
- Setting time is 24 hours at 37 °C⁵.

4 Removal of root canal filling

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

5 Hygiene

5.1 Ribbon® syringe

Cross-contamination.

Infection.

1. The syringe cannot be reprocessed.
2. To prevent the syringe from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringe is handled with clean/disinfected gloves. Do not reuse syringe if contaminated.
3. Dispose of contaminated syringe in accordance with local regulations.

5.2 Ribbon® mixing tips and Disposa-Shield® protective barrier

The use of protective barriers is an additional precautionary measure against gross contamination but not against all contamination.

1. Right after use, carefully remove protective barrier together with mixing tip without contaminating the device.

Cross-contamination.

Infection.

1. Disposa-Shield® protective barrier and Ribbon® root canal sealer mixing tips are intended for single use only. Do not reuse in order to prevent cross-contamination or malfunction.
2. Discard in accordance with local regulations.

5.3 Cleaning

1. Clean spatulas, mixing slabs and instruments immediately after use with alcohol or acetone.

5.4 Disposal

Dispose of in accordance with local regulations.

6 Lot number (), expiration date () and correspondence

1. Do not use after expiration date.
ISO standard is used: "YYYY-MM" or "YYYY-MM-DD".
2. The following numbers should be quoted in all correspondence:
 - Reorder number
 - Lot number
 - Expiration date
3. Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local regulations.





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³ Ribbon® Mixing Tips, Reorder SKU RIBTIPS.

⁴ Internal test method.

⁵ Measured according to ISO 6876:2001 (E). The complete polymerization needs 7 days at 37 °C.