



US

INSTRUCTIONS FOR USE

NexTemp®

Non-Eugenol, Temporary Resin Cement with Fluoride, Potassium Nitrate and Chlorhexidine



Inspired solutions for daily dentistry®



Manufacturer:
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Intended use / Indications for use:

Premier Temporary Cement is recommended for the cementation of temporary crowns, bridges, inlays and onlays.

Product Description:

NexTemp® is a resin based temporary cement for the short-term cementation of temporary or provisional prosthesis. NexTemp is designed to provide secure retention and to be removed without difficulty at the appropriate time. The eugenol-free formula contains fluoride, potassium nitrate, and Chlorhexidine. The resin matrix provides a tight marginal seal that resists washout due to its insolubility in an aqueous environment. Available in opaque and clear shades.

Contents:

NexTemp® is available in various kit configurations to match the clinical preferences:

Premier® NexTemp® Shade Opaque

Item No.	Product Configurations
3001470	NexTemp Bulk Package: Four(4) -5ml Automix Syringes,
3001471	NexTemp Standard Package: One(1) -5ml Automix Syringe, 10 Mix Tips
3001451	Package of 25 – Automix Syringe tips

Premier® NexTemp® Shade Clear

Item No.	Product Configurations
3001473	NexTemp Bulk Package Four(4) -5ml Automix Syringes,
3001472	NexTemp Standard Package: One (1) -5ml Automix Syringe, 10 Mix Tips

Contraindications:

Do not use NexTemp® in cases of:

- As a temporary filling material nor is it to be used for pulp capping.
- Patients with known sensitivity or allergy to resins. Wash exposed area completed to remove material. If an allergic reaction is observed, consult a physician immediately and discontinue use with this patient.
- As a temporary cement in contact with fresh restoration made from dual-cure or self-cure core build-ups materials or composites resins.
- Eugenol containing temporary cement remains on tooth preparation or abutment prior to use of NexTemp.

Precautions:

- Disposable tips are designed for single patient use only. Do not re-use a mix-tip.
- Working & setting times will vary based on temperature, humidity, and product age and storage conditions.
- Use a protective plastic sheath barrier on the syringe in order to mitigate potential cross-contamination between patients.
- Avoid contamination of product. Do not mix components with those of other materials. Do not return dispensed components to their original container. Dispose of leftover material properly.
- Avoid sunlight or nearby heat sources. Shelf life will be reduced if not stored properly.
- Corrective dental procedures may be necessary if not all excess sub-gingival cement is removed.
- Prescription device, Rx only.

WARNINGS:

- Eugenol-containing materials could inhibit the polymerization of NexTemp.
- For use by a trained dental professional only.
- Do not use after the shelf life period indicated on product labeling/packaging.

Adverse Reactions:

Adverse reactions may include but are not limited to:

- Inflammation of soft tissue.
- Allergic reactions to NexTemp® material. Wash exposed area completed to remove material. If an allergic reaction is observed, consult a physician immediately and discontinue use with this patient.
- Pain, discomfort, and/or abnormal sensations due to the presence of NexTemp®.

If a serious incident has occurred in relation to the device, please report the incident to the Manufacturer and/or competent authority of the Member State where the device was used.

Prior to Use:

- Disinfect syringe dispensers using an intermediate level disinfection process (liquid contact) as recommended by the Centers for Disease Control and use a protective plastic sheath barrier on the syringe.
- Ensure a new tip placed on the dispensing end for each use.

Materials:

Non-Eugenol resin formulation with Fluoride, Potassium Nitrate and Chlorhexidine.

Directions for Use (Please follow carefully)

1. Complete tooth preparation and fabrication of the temporary restoration before extruding the mixed cement.
2. Dry and isolate the prepared tooth. Be careful not to desiccate or over-dry the preparation.
3. Remove cap from dual barrel automix syringe and set aside. Extrude a very small portion of the unmixed material to ensure unobstructed flow from both the base and catalyst components of the respective barrels.
4. Attach automix dispensing tip and lock in place with a quarter turn.
5. Extrude a thin layer of the auto-mixed cement on to the cleaned, inside surface of the temporary restoration. You have approximately 45 seconds of working time after extruding the mixed cement.
6. Firmly seat the temporary restoration in place. Initial gel-set occurs within 2 to 2.5 minutes after seating. Cleaning of excess cement should be initiated immediately after this gel-set phase.
7. Final cement set occurs between 4 and 5 minutes after seating of the temporary restoration. Final set time is determined intraorally. Ambient set times vary and are not representative of clinical conditions.
8. Remove used mixing tip from dual barrel automix syringe and replace with original cap.

Optional Hand-Mixing Directions:

1. Complete tooth preparation and fabrication of the temporary restoration before extruding the mixed cement.
2. Dry and isolate the prepared tooth. Be careful not to desiccate or over-dry the preparation.
3. Remove cap from dual barrel automix syringe and set aside. Extrude a very small portion of the unmixed material to ensure unobstructed flow from both the base and catalyst components of the respective barrels.
4. Place dispensing end of dual barrel syringe onto clean glass slab or clean mixing pad. Extrude the appropriate amount of base and catalyst onto the selected mixing surface. Be sure to avoid cross contaminating the openings of the respective base and catalyst barrels. Recap syringe with original closure.
5. Using a clean spatula or mixing stick, mix the two components into a homogeneous paste.
6. Using the mixing stick or brush, apply a thin layer of the mixed cement on to the cleaned, inside surface of the temporary restoration. You have approximately 45 seconds of working time after extruding the mixed cement.
7. Firmly seat the temporary restoration in place. Initial gel-set occurs within 2 to 2.5 minutes after seating. Cleaning

of excess cement should be initiated immediately after this gel-set phase.

8. Final cement set occurs between 4 and 5 minutes after seating of the temporary restoration. Final set time is determined intraorally. Ambient set times vary and are not representative of clinical conditions.

Storage:

- NexTemp® can be stored in a temperature range 4°C(39°F) - 24°C(75°F).
- Do not store at temperature over 24°C (75°F). DO NOT FREEZE.
- Allow material to warm to room temperature prior to use.

Shelf Life:

- NexTemp® has a shelf life of 2 years (24 months) from the date of manufacturing.
- Do not use after product has expired. See expiry date on the product label.

For Further Information:

To obtain SDS or IFU, visit premierdentalco.com or call Premier at 610-239-6000.

Symbols	Symbol Meaning
	Expiry date
	Manufacturer
	Batch number
	Caution: See instructions for use
	The upper and lower limits of temperature of use, storage and transportation
	Irritant (Skin and Eye) Skin Sensitizer.
	Keep away from sunlight
	See IFU on premierdentalco.com
Rx ONLY	"CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician