

FlexiTemp PLUS

Light Curing Temporary Filling Material

Instructions for Use


IMPORTANT

Read this 'Instructions for Use' document before handling. This product is for use by dental professionals only.

SPECIALLY FORMULATED FOR USE IN DENTISTRY

DESCRIPTION

FlexiTemp PLUS is a light curing, bioinert material for temporary use based on resin and inorganic filler. FlexiTemp PLUS has an easily packable consistency.

Product Name	FlexiTemp PLUS
Company Name	Perfection Plus Ltd
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PRODUCT CODE - REF

010/1026 Flexi Temp PLUS 2 x 4g Syringe

COMPOSITION

Monomer 40-60%, aluminium oxide 10-30%, silicon dioxide 10-30%, coinitiator <1%, photoinitiator <1%, inhibitor <1%, pigment <1%.

FlexiTemp PLUS does not contain medicinal substances, including human blood or plasma derivate; tissues or cells, or their derivates, of human origin; tissues or cells of animal origin, or their derivates, as referred to in Regulation (EU) No. 722/2012; substances which are carcinogenic, mutagenic, toxic to reproduction or having endocrine-disrupting properties.

PERFORMANCE CHARACTERISTICS

Light curing 20-40 seconds
Depth of cure 1.74±0.05 mm

INTENDED PURPOSE AND CLINICAL BENEFITS

FlexiTemp PLUS restores/improves for temporary aesthetic appearance of restorable tooth; restores/maintains for temporary dental function of restorable tooth; protects for temporary biological structures of restorable tooth and adjacent tissues.

CLINICAL INDICATIONS

For temporary fillings.

CONTRA-INDICATIONS

Patients who have a history of severe allergic or irritation reactions to product or to any of the ingredients.

RESTRICTIONS TO COMBINATIONS

FlexiTemp PLUS should not be used with products containing eugenol as eugenol may disturb the polymerization process.

UNDESIRABLE SIDE EFFECTS

In susceptible individuals, FlexiTemp PLUS may cause allergic or irritation reactions (skin, eye, mucosa).

RESIDUAL RISKS

Risk control measures have been implemented and verified, risk is reduced as far as possible, the overall residual risk is judged to be acceptable.

PATIENT TARGET GROUP

No restrictions known regarding patient population, their age and general health conditions. There may be children, middle aged or elderly patient.

INTENDED PART OF THE BODY OR TYPES OF TISSUES OF BODY FLUIDS

Part of the body – mouth. Tissues or body fluids contacted by the device – tooth, saliva.

INTENDED USER

FlexiTemp PLUS is developed for professional use in dentistry only. Its user only licensed doctor who has knowledge how to use common dental materials. There is no need for specific training.

STERILITY

FlexiTemp PLUS is delivered non-sterile. There is no need of any preparatory sterilization, cleaning or disinfection, preventive, regular maintenance or calibration to ensure that the device operates properly and safely during its intended lifetime. However, do not use if primary package is damaged.

USE ENVIRONMENT

FlexiTemp PLUS is designed to be used in dental office where ambient temperature is 18-25°C. Dispensed amount of material is suitable for single use (only for one patient). Do not re-use. Dispensed amount kept not in original package may lead to loss of function.



CONSUMABLE COMPONENTS AND ACCESSORIES

No consumable components and accessories are supplied with the device.

INSTRUCTION FOR USE

1. Using suitable instrument take out a little of the material from the syringe and immediately close syringe cap.
2. Form a ball and place direct into cavity and adapt as necessary.
3. Do not apply layers more than 2mm thick.
4. Light cure for 20-40 seconds depending on layer thickness. Use LED polymerization lamp with light intensity 1200mW/cm². Some lamps with higher intensity could require less time of polymerization, follow manufacturer's instruction for use.

WARNINGS

After the desired amount of material extruded, the syringe cap must be closed immediately, so that the material is not unlighted. Do not use FlexiTemp PLUS for patients who have a history of severe allergic or irritation reactions to product or to any of the ingredients. FlexiTemp PLUS does not emit radiation and does not cause any electromagnetic interferences.

PRECAUTIONS!

It is recommended to use cofferdam during application of the product.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.



IF ON SKIN OR MUCOSA: Wash with plenty of water. If skin/mucosa irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse.

IF SWALLOWED: Rinse mouth. Call a Poison Centre or doctor/physician if you feel unwell.

Wash hands thoroughly after handling. Use only in a well-ventilated area. It is recommended to wear protective gloves/protective clothing/eye protection/face protection for doctor and patient.

Precautions to be taken in the event of changes in the performance of the device:

If, during the use of the product, any abnormal product performance characteristics are noticed: non-homogenous, uneven consistency, product does not harden or does not adhere on the applied surface while curing with light or any by-products/phases are released during the time of curing, or sudden acute pain occur on application site, or if any other abnormal behaviour of the product noticed while manipulating the device, that is not mentioned above, discontinue to use immediately.

Remove the restoration from the tooth cavity with suitable dental instrument do not let the product be swallowed. Ask patient how she/he is feeling. If patient notices any undesirable side-effects, immediately call a local poison centre. Collect all available remaining supplies, do not use them again and keep them out of reach in a safe place until further notice. Contact the manufacturer immediately and report of any noticed changes in the performance of the product.

SHELF-LIFE

Shelf-life of FlexiTemp PLUS is 4 years from the date of manufacture. Do not use after the expiry date. See packing for expiry date.

STORAGE

Keep product tightly closed in dry well-ventilated place at 4-28°C. Protect from direct sunlight and heat sources. Do not freeze. Keep out of the reach of children!



DISPOSAL

Dispose of contents/container to as required by national regulatory requirements.

VIGILANCE

If any serious incident that has occurred in relation to the device report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

FlexiTemp PLUS is safe and performs as intended if it used in accordance with manufacturer's instruction for use.













MANUFACTURERS RESPONSIBILITY

Our products have been developed for professional use in dentistry. As the application of our products is beyond our control, the user is fully responsible for the application.

VALIDITY

Upon publication of this instruction for use, all previous versions are superseded.

EXPLANATION OF SYMBOLS USED

	Catalogue number
LOT	Batch code
	Use by date
	Manufacturer
	Distributor
	Importer
	Consult Instructions for use
	Do not re-use
	Non Sterile
	Avoid direct sunlight
	Temperature limit
	Caution
	Medical Device



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