Flow-E Flowable Composite
Light Curing Nano Flowable Composite

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
Flow-E Flowable Composite is a light curing nano flowable, bioinert, radiopaque composite under the Vita* shades. Flow-E Flowable Composite is a high aesthetic, highly resistant, superior polishability product with optimal flow characteristics.

Product Name	Flow-E Flowable Composite
Company Name	Perfection Plus Ltd
Company Address	6 Westwood Court, Brunel Road, Totton, Hampshire, SO40 3WX, UK
Company Phone No.	+44 (0) 2380 866 677

PRODUCT CODE - REF
010/1031 Flow-E Flowable Composite 2g Syringe A2
010/1032 Flow-E Flowable Composite 2g Syringe A3

COMPOSITION
Dental glass grinded 50-70%, methacrylate mixture 30-40%, silicon dioxide 1-5%, coinitiator <1%, photoinitiator <1%, stabilizer <1%, inhibitor <1%, opacifier <1%,pigment 1%.

Flow-E Flowable Composite 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 cure	20-30 seconds
Depth of Cure	3.24 ± 0.03mm
Flexural strength	110.2 ± 4.1 MPa
Water sorption	17.10 ± 0.20ug/mm^3
Water solubility	0.00 ± 0.00 ug/mm^3
Polymerization shrinkage	4.5±0.15%

INTENDED PURPOSE AND CLINICAL BENEFITS
Flow-E Flowable Composite restores/improves the aesthetic appearance of a restorable tooth; restores/maintains dental function of restorable tooth; protects biological structures of a restorable tooth and adjacent tissues.

CLINICAL INDICATIONS
- For restorations of class III, IV and V cavities; root surface caries restorations;
- For sealing pits and fissures;
- For initial placement in class I and II cavities.

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

RESTRICTIONS TO COMBINATIONS
Flow-E Flowable Composite should not be used with products containing eugenol as eugenol may disturb the polymerization process.

UNDESIRABLE SIDE EFFECTS
In susceptible individuals, Flow-E Flowable Composite may cause allergic or irritation reactions (skin, eye, mucosa, respiratory tract irritation).

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

Floe-E Flowable Composite is developed for professional use in dentistry only. It should be used only by a licensed doctor who has knowledge how to use common dental materials. There is no need for specific training.

STERILITY

Flow-E Flowable composite 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

Flow-E Flowable composite 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 accessories are supplied with the device. Consumables, such as application tips, are supplied with the device

INSTRUCTION FOR USE

CAVITY PREPERATION:

1. Prepare cavity as always.
2. Clean the surface with oil-free prophylaxis paste.
3. For deep cavities use calcium hydroxide liner or glass ionomer base lining cement.

ETCHING, BONDING:

1. Apply layer of etch to surface to be etched. Leave etch in place for 15 seconds (dentine), 30 seconds (enamel). Rinse with water and dry with air. Avoid over drying dentin.
2. Apply a layer of adhesive immediately onto etched surface, follow manufacturer's instruction for use.

SYRINGE PREPARATION:

1. Remove syringe cap.
2. Promptly and carefully attach the dispensing tip to the syringe.
3. Test flow of materials from tip before using intraorally.

PLACEMENT OF FLOW-E FLOWABLE COMPOSITE:

1. Before bringing the syringe to the mouth, remove the air from the dispensing tip. To remove air from the tip, with the tip pointing upwards, gently push forward the syringe plunger. If the air is still inside the dispensing tip, air bubbles may be removed at the time of injection.
2. Delicately push on plunger and apply layer of material into the cavity. Do not force plunger.
3. Do not apply layers more than 2 mm deep.
4. Light cure for 20-30 seconds (depends on layer depth). Use LED polymerization lamp with light intensity 1200mW/cm2 in full mode, not ramp or pulse mode. Some lamps with higher intensity could require less time of polymerization, follow manufacturer's instruction for use. Finish restoration.

WARNINGS

After the desired amount of material extruded, immediately remove application tip and close the syringe cap, so that the material is not unlighted. The material is sensitive to light. Avoid too long manipulation time under intensive lighting. Do not use Flow-E Flowable Composite for patients who have a history of a history of severe allergic or irritation reactions to product or any of the ingredients. Flow-E Flowable Composite 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.

IF INHALED: Remover person to fresh air and keep comfortable for breathing.

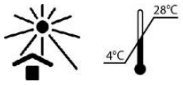
Wash hands thoroughly after handling. Use only in a well-ventilated area. It is recommended to wear protective gloves/protective clothing/eye protection/face protection for doctor and patient.

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

If any abnormal product performance characteristics are noticed during the use of the product: non-homogenous, non-flowable, uneven consistency, does not cover the tooth surface evenly, product does not harden or composite colour change is observed in a moment of light-curing, i.e. the composite does not correspond to the intended shade specified by the manufacturer or/and by-products/phases are released during 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 any noticed changes in the performance of the product.

SHELF-LIFE
Shelf-life of Flow-E Flowable Composite 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
Flow-E Flowable Composite is safe and performs as intended if it is used in accordance to manufacturer's instruction for use. Summary of safety and clinical performance is available through manufacturer's website www.i-dental.lt/sscp/ until European Database on Medical Devices (EUDAMED) comes online.

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

REF	Catalogue number
LOT	Batch code
	Use by date
	Manufacturer
	Distributor
	Importer
	Consult Instructions for use
	Do not re-use
NON STERILE	Non Sterile
	Avoid direct sunlight
28°C 4°C	Temperature limit
	Caution
MD	Medical Device

* Registered trademark of the Vita Zahnfabrik H.Rauter GmbH & Co. KG, Bad Sackingen, Germany.

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