infinix™

bulk fill flow composite

INSTRUCTIONS FOR USE

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I. Introduction

Infinix™ Bulk Fill Flow Composite is a restorative base dental material with high depth of cure for bulk fillings. It is injectable, visible-light activated, radiopaque, flowable composite. This flowable material is semi translucent enabling a higher depth of cure. The composite is packed in multi-dose syringe (2g). The product is supplied in shade A1, which corresponds to the VITA Classical Shade Guide. Infinix™ Bulk Fill Flow Composite is a heterogeneous blend of polymer matrix and filler. The matrix consists of Urethane dimethacrylate (UDMA), Bisphenol A-glycidyl methacrylate (Bis-GMA), Ethoxylated bisphenol A dimethacrylate (Bis-EMA) and Triethylene glycol dimethacrylate (TEGDMA). The filler is a blend of small-sized glass powder (40nm-3µm), silica dioxide, Quaternary Ammonium Silica dioxide (QASi) and pigments. The total content of inorganic fillers is 60-70wt.%.

II. Symbols Glossary

The following symbols may appear in the product documentation or on the labels attached to the product:

Symbol	Symbol Name	Symbol Description
	Manufacturer	Indicates the name and address of the manufacturer.
	Date of manufacture	Indicates the date when the device was manufactured.
	Use by date	Indicates the date after which the medical device is not to be used.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number	Indicates the manufacturer's catalog number so that the devicecan be identified.
	Temperature limitations	Indicates the temperature limits to which the medical device can be safely exposed.
	Keep dry	Indicates a medical device that needs protection from moisture.
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	Caution	CAUTIONS are directions which if not followed could cause damage to the product described in this Instructions for Use and/or any other
	Consult information for user manual	Indicates the need for the user to consult the instructions for use.
	Prescription Device	Caution: In the United States, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Do not reuse	Disposable tips.

III. Indications for Use

1) Base under Class I and II direct restorations.
2) Liner under direct restorative materials.
3) Pit and fissure sealant.
4) Restoration of minimally invasive cavity preparations (including small, non-stress-bearing occlusal restorations).
5) Class III and V restorations.
6) Blocking out of undercuts.
7) Repair of small enamel defects.
8) Repair of small defects in esthetic indirect restorations.
9) Repair of resin and acrylic temporary materials.
10) As a core build-up where at least half the coronal tooth structure is remaining to provide structural support for the crown.

The addition of the QASi particles to the Bulk Fill Flow Composite reduces demineralization, which is part of the caries-formation process.

IV. Intended user

The device is designed to be used by dentists only (Rx only).

V. Patient Target Group

Children and adults regardless of gender.

VI. Contraindication

Infinix™ Bulk Fill Flow Composite is contraindicated in patients with a history of hypersensitivity to methacrylate monomers.

VII. Precautionary Information for Patient

This product contains substances that may cause an allergic reaction by skin contact with certain individuals. Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If an allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of this product.

VIII. Precautionary Information for Dental Personnel

This product contains substances that may cause an allergic reaction by skin contact with certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed. For MSDS information please contact your local subsidiary.

IX. Instructions for Use

9.1 PREPARATION

9.1.1 PROPHY
Teeth should be cleaned with pumice and water to remove surface stains.

9.1.2 SHADE SELECTION
The Infinix™ Bulk Fill Flow Composite shade A1 is based on the VITA classical shade guide. For sealants, a contrasting shade may be desirable to enhance detection.

Note As Infinix™ Bulk Fill Flow Composite is semi translucent, the location of the restoration, underlying tooth color or adjacent restorations may influence the final appearance of the liner/base.

9.1.3 ISOLATION
A rubber dam is the preferred method of isolation. Cotton rolls and an evacuator can also be used.

9.1.4 CAVITY PREPARATION
Prepare cavity using standard techniques. Dry by gentle blowing with oil free air.

9.2 DIRECT RESTORATION

9.2.1 MATRIX BAND
Formation of tight proximal contacts is accomplished solely through careful matrix technique. Wedging is needed to provide a tight gingival seal and to create a separation between teeth to compensate for thickness of the matrix band. Where possible, use of a pre contoured sectional matrix band is preferred. However, a thin circumferential dead-soft band can be used when appropriate. The band should be burnished to ensure proper proximal contour as Infinix™ Bulk Fill Flow Composite will not hold the band during placement.

9.2.2 PULP PROTECTION
Areas of deep cavity excavation and/or if a pulp exposure has occurred and situation warrants a direct pulp capping procedure, it is recommended to use a minimum amount of pulp/dentin protector (apply a calcium hydroxide-based preparation to areas in close proximity of the pulp and cover it with an adequate lining).

9.2.3 INFINIX ADHESIVE SYSTEM TREATMENT
To bond Infinix™ Bulk Fill Flow Composite to tooth structure and to obtain optimal

results, the use of Infinix™ Universal Bond (Prime and Bond) is recommended. Please refer to the respective Instructions for use. After curing the adhesive, continue to maintain isolation from blood, saliva and other fluids and proceed immediately to placement of Infinix™ Bulk Fill Flow Composite.

Note Follow the Infinix adhesive system instructions for use for recommended silane treatment during repair of ceramic restorations followed by the adhesive application.

9.3 APPLICATION OF INFINIX™ BULK FIL FLOW COMPOSITE

9.3.1 SYRINGE DELIVERY
Infinix™ Bulk Fill Flow Composite can be delivered directly from the dispensing tip.

Note Protective eyewear for patients and staff is recommended when using the dispensing tip.

1) Prepare the dispensing tip: Remove cap and save. Twist the pre-bent disposable dispensing tip securely onto the syringe. Holding the tip away from the patient and any dental staff, express a small amount of Infinix™ Bulk Fill Flow Composite to assure that the delivery system is not plugged.
2) If plugged, remove the dispensing tip and express a small amount of Infinix™ Bulk Fill Flow Composite directly from the syringe. Remove any visible plug, if present, from the syringe opening. Replace dispensing tip and again express composite.
3) Infinix™ Bulk Fill Flow Composite may be extruded onto a dispensing pad and applied with an appropriate instrument.

9.4 PLACEMENT

9.4.1 Avoid intense light in the working field. Exposure of paste to intense light may cause premature polymerization.
9.4.2 Dispense Infinix™ Bulk Fill Flow Composite: Start dispensing in the deepest portion of the preparation, holding the tip close to the preparation surface. As the material is extruded, slowly raise the tip so it is slightly above the dispensed material to minimize air entrapment. Do not allow the tip to be immersed in the material. For proximal areas, hold the tip against the matrix to aid material flow into the proximal box.
9.4.3 Base/liner application: Allow for at least 2mm on the occlusal cavosurface for the universal composite (Infinix™ Universal Composite is recommended). These occlusal increments provide strength, wear resistance and esthetic qualities needed for posterior restorations.
9.4.4 Core build up: Syringe material into undercut areas, around pins, around posts and fill the preparation.
9.4.5 Sealant applications: Flow material onto the prepared surface.
9.4.6 Light cure restorative as indicated in Section 9.5.

9.5 CURING

This product is intended to be cured by exposure to a halogen or LED light with a minimum intensity of at least 1000 mW/cm^2 in the 400-500 nm range. Cure each increment by exposing its entire surface to a high intensity visible light source. Hold the light guide tip as close to the restorative as possible during light exposure.

Shades	Increment depth	Cure time
		All halogen or LED lights (with output ≥ 1000 mW/cm^2)
A1	4 mm	20 sec.

Note
- Material should be placed and light cured in layers.
- Inefficient exposure to the curing light may cause incomplete polymerization.
- When using a metal matrix, additionally polymerize the composite material from the buccal or the lingual/palatal aspect after removing the matrix.

9.6 COMPLETE THE RESTORATION

9.6.1 Base/Liner application: To obtain optimal results, Infinix™ Universal Composite can be used directly over the cured Infinix™ Bulk Fill Flow Composite. Follow the manufacturer's instructions regarding placement, curing, finishing, occlusal adjustment, and polishing.

Note For best results, it is recommended to use Infiix™ Bulk Fill Flow Composite in combination with other Infinix restorative materials (please refer to the respective instructions for use).

9.6.2 Pit and fissure sealants: Gently remove the inhibited layer remaining after light curing with slurry of pumice or polishing paste.
9.6.3 Core build up:
1) Infinix™ Bulk Fill Flow Composite is compatible with commonly used impression materials when surface inhibition layer is removed.
2) Infinix™ Bulk Fill Flow Composite should be kept wet with saliva or lubricated to prevent bonding to chemical-cure provisional materials.

9.6.4 Direct Restorative Application:
1) Contour restoration surfaces with fine finishing diamonds, burs or stones.
2) Check the occlusion with a thin articulating paper. Examine centric and lateral excursion contacts. Carefully adjust occlusion by removing material with a fine polishing diamond or stone.
3) Polish with finishing and polishing systems or with white stones, rubber points or polishing paste where discs are not suitable.

Note After polishing, re-bonding by applying additional Infinix™ Bond is recommended and light cure it.

Warning!
Avoid contact of unpolymerized Infinix™ Bulk Fill Flow Composite with skin, mucous membrane and eyes. Unpolymerized Infinix™ Bulk Fill Flow Composite may have a slight irritating effect and may lead to a sensitization against methacrylates. Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

X. Storage and Use

- Operetion and storage temperature is 15-25°C/59-77°F.
- See the outer package for expiration date.
- Do not expose restorative materials to elevated temperatures, or to intense light.
- Do not store materials in proximity to eugenol containing products.
- In the form of a syringe, after use of sheathed syringe, remove delivery tip and sheath by grasping on the hub of the delivery tip through the sheath; twist and remove tip along with sheath. Discard used syringe tip and replace with syringe storage cap.
- After removal of the delivery tip and sheath, disinfect this products using an intermediate level disinfection process (liquid contact) as recommended by the Centers for Disease Control and endorsed by the American Dental Association, Guidelines for Infection Control in Dental Health-Care Settings, 2003. MMWR, December 19, 2003:52(RR-17), Centers for Disease Control and Prevention.

XI. Disposal

Used packages are considered as bio-hazard and need to be discarded as bio-hazard waste in accordance with local regulations.

XII. Customer Information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Caution
U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

LIMITED WARRANTY AND LIMITATION OF LIABILITY
Nobio Ltd. ("Nobio") warrants that the product shall be free from defects in material and workmanship prior to its stated expiration date. In case that the product is found by Nobio to be defective, user's sole remedy will be limited to replacement of the defective product, in accordance with Nobio's then current RMA policy. No cash refunds will be allowed for a returned product. Nobio is not responsible for costs incurred for removal or placement of dental restorations, including labor, practice expenses, or pain and suffering. Without derogating from the foregoing, replacement resulting from accident, neglect, abuse, failure of supportive tooth or tissue structure is not covered under the terms of this warranty. Nobio will not be liable for any loss or damage, direct, consequential, special or otherwise, arising out of the application or use of or the inability to use the product. Before using, the user shall determine the suitability of the products for the intended use and the user assumes all risk and liability whatsoever in connection therewith. Subject to the full compliance with the applicable use instructions, in the event that, despite the above, a court with valid jurisdiction or other competent authority declares that Nobio is in any way liable, then Nobio's total aggregate liability in connection with the application or use or inability to use this product, shall in no event exceed the amounts paid by the user to Nobio.

Physical Properties
- Compressive strength: ≥ 180 MPa
- Flexural strength: ≥ 85 MPa

Note Any serious incident that has occurred in conjunction to our device, must be reported to Nobio (at the address listed below) and to the competent authority of the member state in which the user is established.

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