ENGLISH

Bulk EZ PLUS®

Dual-Cure Bulk-Fill Composite with IntelliTek® Technology

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

Bulk EZ PLUS® is an easy-to-place, dual-cure, bulk-fill composite that offers an unlimited depth of cure in a single application without multiple layers and light-curing when allowed to self-cure. Bulk EZ PLUS utilizes 80 nm spherical fillers, combining flowable cavity adaptation with high strength, wear resistance, polishability, and a superior chameleon effect —all in one simple step. Its proprietary self-cure IntelliTek® Technology is designed to specifically control and direct shrinkage for the purpose of eliminating microleakage in restorations. Additionally, Bulk EZ PLUS is highly color-stable over time and compatible with a wide variety of bonding agents without the need of dual-cure activators or primers.

FEATURES

- Unlimited depth of cure
- Directed shrinkage virtually eliminates microleakage
- 80nm spherical zirconia fillers offer higher wear resistance, polishability, and chameleon effect
- High physical strength and esthetics make a capping layer unnecessary
- A1/B1, A2/B2, A3/A3.5/B3, C2/C3, Bleach Opaque, and Core White shades (per the VITA Shade Guide) allow for excellent esthetics and core build up applications

INDICATIONS FOR USE

Bulk EZ PLUS is a dual-cure (auto-cure with light-cure acceleration) resin-based dental restorative that, when applied to dental surfaces pretreated with suitable primers or adhesives, is indicated for use as:

- Direct restoration, Class I through VI
- Cavity liner
- Core build-up
- Luting Posts
- Crowns
- Any application where light transmission may be inadequate.

SINGLE-USE ACCESSORIES

Mixing tips are single-use, and are provided non-sterile. The mixing tips must not be reused. The single use accessories may not function as intended if re-sterilized and may result in an improper procedure and lead to improper function or failure of the device. Dispose of after use in accordance with instructions below.

MULTI-USE DEVICES

Syringes are multi-use devices and are provided non-sterile. Always use a shield or other means to prevent exposure or transfer of blood, tissue, or saliva that may contain infectious disease. Use in accordance with instructions below.

WARNINGS AND PRECAUTIONS

1. Keep away from sunlight or ambient light; Replace cap after each use.
2. Use a halogen curing light with a minimum output of 600 mW/cm2. Other light sources or intensities require an adjustment to the cure time. See curing light manufacturer's instructions.
3. Uncured resin material can cause irritation, especially in people known to be allergic to methacrylates. Wash hands after handling material.
4. The composite is formulated to be used at room temperature. Shelflife at room temperature is stated on the syringe.
5. Do not store the composite material in proximity of eugenol-containing products. Do not let the composite come into contact with material containing eugenol.Eugenol can impair the hardening of the composite and cause discoloration.
6. Do not expose materials to elevated temperatures or intense light.
7. Avoid cross-contamination by using a new mixing tip for every patient and using a barrier sleeve.

APPLICATION FOR RESTORATIONS

TOOTH PREPARATION:

1. Isolate tooth to prevent contamination of blood and/or saliva. Suggested use includes a rubber dam, Isolite® System, or Zest's Dam Cool™ light-cured dental dam.
2. Complete conservative cavity preparation with conventional means or with a hydro-abrasive system such as Zest's PrepStart™ H2O.
3. Use of Zest's Caries Finder™ or similar is recommended to accurately visualize caries removal without unnecessary tooth reduction.
4. Place sectional matrix such as Zest's Mega V™ Ring contact matrix system to obtain natural interproximal contour as needed. Ensure good adaptation to minimize clean-up.
5. Apply etchant such as Zest's Sure Etch™ or similar per manufacturer's instructions.
6. Apply bonding agent such as Zest's Prelude™ or Prelude One™ per manufacturer's instructions.

Note: Bulk EZ PLUS is compatible with a wide variety of methacrylate-based dental bonding agents/systems as well as etching techniques without the use of dual-cure activators or primers.

COMPLETING THE RESTORATION:

1. Remove the twist-off cap.
2. Before each use, bleed material until both base and catalyst are extruded out.
3. Manually bend the metal cannula on the mixing tip to the desired angle.
4. Securely attach a mixing tip by twisting it onto the head of the syringe, bleed a small amount of material to ensure even mixing. To avoid cross-contamination, use a new mixing tip for every patient.
5. To avoid cross-contamination, use a barrier sleeve to cover the syringe.

Note: Avoid strong direct light on the transparent mixing chamber as it could speed up the thickening process.

6. Immediately place the mixing tip at the deepest part of the preparation and fill while keeping tip within the material to avoid introducing air. Sculpt to the desired contour as the material self-cures using the syringe tip or composite instrument.
7. Allow the material to self-cure for at least 90 seconds. Subsequent light-curing of the top surface for 10 seconds is optional.
8. Proceed to finishing and polishing steps.

Note: It is recommended to leave the Bulk EZ PLUS mixing tip on the syringe as a cap until the next application.

9. Polish to a high gloss with discs or composite polishing points. Interproximal finishing/polishing is accomplished with fine grit finishing/polishing strips according to manufacturer's instructions.

APPLICATION FOR CORE BUILD-UP

TOOTH PREPARATION:

1. Isolate tooth to prevent contamination of blood and/or saliva. Suggested using includes a rubber dam, Isolite® System, or Zest's Dam Cool™ light-cured dental dam.
2. Complete conservative cavity preparation with conventional means or with a hydro-abrasive system such as Zest's PrepStart™ H2O.
3. Use of Zest's Caries Finder™ is recommended to accurately visualize caries removal without unnecessary tooth reduction.
4. Place sectional matrix such as Zest's Mega V™ Ring contact matrix system or crown form to achieve optimal contour and shape.
5. Apply etchant such as Zest's Sure Etch™ per manufacturer's instructions.

Note: Prior to bonding in deep cavities in areas close to pulp, use calcium hydroxide or other pulp protectants.

6. Apply bonding agent such as Zest's Prelude™ or Prelude One™ per manufacturer's instructions.

Note: Bulk EZ PLUS is compatible with a wide variety of methacrylate-based dental bonding agents/systems as well as etching techniques without the use of dual-cure activators or primers.

COMPLETING THE CORE BUILD-UP:

1. Remove the twist-off cap.
2. Before each use, bleed material until both base and catalyst are extruded out.
3. Manually bend the metal cannula on the mixing tip to the desired angle.
4. Securely attach a mixing tip by twisting it onto the head of the syringe, bleed a small amount of material to ensure even mixing. To avoid cross-contamination, use a new mixing tip for every patient.
5. To avoid cross-contamination, use a barrier sleeve to cover the syringe.

Note: Avoid strong direct light on the transparent mixing chamber as it could speed up the thickening process.

6. Immediately place the mixing tip at the deepest part of the preparation and fill while keeping tip within the material to avoid introducing air. With crown forms, fill and place.
7. Use diamond or carbide burs for final crown preparation.

APPLICATION FOR POST CEMENTATION

TOOTH PREPARATION:

1. Isolate tooth to prevent contamination of blood and/or saliva. Suggested using includes a rubber dam, Isolite® System, or Zest's Dam Cool™ light-cured dental dam.
2. Complete conservative cavity preparation with conventional means or with a hydro-abrasive system such as Zest's PrepStart™ H2O.
3. Use of Zest's Caries Finder™ or similar is recommended to accurately visualize caries removal without unnecessary tooth reduction.
4. Place sectional matrix such as Zest's Mega V™ Ring contact matrix system or crown form to achieve optimal contour and shape.
5. Apply etchant such as Zest's Sure Etch™ per manufacturer's instructions.

Note: Prior to bonding in deep cavities in areas close to pulp, use calcium hydroxide or other pulp protectants.

6. Apply bonding agent such as Zest's Prelude™ or Prelude One™ per manufacturer's instructions.

Note: Bulk EZ PLUS is compatible with a wide variety of methacrylate-based dental bonding agents/systems as well as etching techniques without the use of dual-cure activators or primers.

CEMENTING POSTS:

1. Carry out any preparation procedures necessary for root posts in accordance with the manufacturer's instructions.
2. Prepare the root canal in accordance with the requirements of the respective root post.
3. If the bonding agent used requires an additional etching step, then etch inside the canal using the etching gel per the manufacturer's instructions.
4. Apply bonding agent in accordance with the manufacturer's instructions. If an adhesive system with a light-curing component is used, remove any excess from the canal prior to the application of light. Otherwise, the lumen may be blocked.
5. Apply Bulk EZ PLUS to the canal lumen. When doing so keep the end of the tip constantly immersed in the material. If desired, it is additionally possible to coat the root post with Bulk EZ PLUS. The working time of Bulk EZ PLUS 60 seconds.
6. Set the root post.
7. Using a suitable light, apply light to the material for 10 seconds.
8. Leave the material to harden for approx. 5:00 minutes. This guarantees complete curing, also in the areas that cannot be reached by light.

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CE 2797

ISO 4049 CLASSIFICATION
Type 1; Class 3.

RANGE OF DIMENSIONS OF INORGANIC FILLER PARTICLES (% BY VOLUME TOTAL INORGANIC FILLER)
80nm (60-70%)

RADIO-OPAQUE
Bulk EZ Plus is radio-opaque.

STORAGE
Store at or below 77°F (25°C). Use at room temperature.

DISPOSAL
Dispose of used devices which pose a risk of infection according to facility clinical waste procedures and applicable local and state regulations. To dispose of unused material, replace cap and dispose of in accordance with local and state regulations (refer to SDS as appropriate).

NOTICE TO USERS IN THE EUROPEAN UNION
Any serious incident that has occurred in relation to the device(s) in which this Instructions for Use applies should be reported to the manufacturer identified in this Instructions For Use and the competent authority of the Member State in which the user and/or patient is established.

DEFINITIONS OF SYMBOLS
The following symbols may appear on the product packaging or labeling.

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
	Manufacturer	Indicates the medical device manufacturer	EN ISO 15223-1	5.1.1
EC REP	Authorized representative in the European Community / European Union	Indicates the authorized representative in the European Community / European Union	EN ISO 15223-1	5.1.2
REF	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	EN ISO 15223-1	5.1.6
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	EN ISO 15223-1	5.1.5
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use	EN ISO 15223-1	5.4.3
	Use-by date	Indicates the date after which the medical device is not to be used	EN ISO 15223-1	5.1.4
	Upper Limit of Temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed	EN ISO 15223-1	5.3.6

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
CE 2797	European Mark of Conformity	Indicates device is in conformance with Medical Device Regulation EU 2017/745	MDR EU 2017/745	Annex V
Rx only	Rx only	Caution: U.S. Federal law restricts this device to sale by or on the order of a dentist	US Code of Federal Regulations, Title 21	801.15(c)(1)(i)(F)
	Keep away from sunlight	Indicates a medical device that needs protection from light sources	EN ISO 15223-1	5.3.2
QTY	Quantity	Indicates the number of items within the package	N/A	N/A
MD	Medical device	Indicates the item is a medical device	EN ISO 15223-1	5.7.7
UDI	Unique Device Identifier	Indicates a carrier that contains unique device identifier information	EN ISO 15223-1	5.7.10