

ZNano Shade-Adaptive Universal Nanocomposite

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

ZNano Shade-Adaptive Universal Nanocomposite is a Zirconia-silica filler containing (ca. 73 wt%), light-cured, radio-opaque, true nano-composite (with an average primary particle size of 80 nm) designed for a swift and easy placement of direct restorations in all cavity Classes I to V. The distinct feature of ZNano is derived from its ability to simplify the color-matching process and reduce the inventory of composite materials necessary to achieve life-like esthetics. By seamlessly balancing the chroma and value of one hue with another (eg. A1 with B1), ZNano allows clinicians to recreate the complex topography and optical characteristics of natural teeth using fewer steps and materials. Combining impressive flexural strength (134 MPa) and polishability (ca. 65 G.U.) with easy handling, ZNano creates esthetic, functional, and long-lasting restorations in a simplified and predictable manner.

ZNano Shade-Adaptive Universal Nanocomposite is available in five shades: A1/B1, A2/B2, A3/A3.5/B3, C2/C3 and Bleach/Opaque (OM2), and is delivered in convenient 4 gram syringes and in packages containing 20 x 0.2 gram compules.

INDICATIONS FOR USE

ZNano Shade-Adaptive Universal Nanocomposite is a highly-filled, light-cured, resin-based dental composite material that when applied to the tooth surface pretreated with appropriate dental primers or adhesives is indicated for:

- Direct restorations in cavity Classes I to V
- Composite inlays and onlays
- Reconstruction of damaged teeth, both anterior and posterior
- Diastema closure and correction of the tooth's shape and shade
- Repairing veneers and provisional crown-and-bridge materials

WARNINGS AND PRECAUTIONS

1. ZNano Shade-Adaptive Universal Nanocomposite contains methacrylates which can cause irritation, especially to people known to be allergic to these ingredients.
2. Do not store composite material in proximity of eugenol-containing products, nor let the composite come into contact with materials containing eugenol. Eugenol can impair polymerization of the composite and cause discoloration.
3. Do not expose the material to elevated temperatures or intense light.
4. A single compule of the material should be used for one patient only and applied with a suitable composite gun using a uniform pressure.

APPLICATION

TOOTH PREPARATION

1. Isolate tooth to prevent contamination of blood and/or saliva. Suggested systems include a rubber dam, Isolite® System, or Zest's Dam Cool™ light-cured dental dam.
2. Complete conservative cavity preparation with conventional means or using an air abrasion system such as Zest's PrepStart™ H2O.
3. Identify caries using the recommended Zest's Caries Finder™ to accurately visualize caries removal without any unnecessary tooth reduction.
4. Place sectional matrix such as Zest's Mega V™ Ring Contact Matrix to obtain natural interproximal contours, ensure good adaptation, and to minimize the clean-up.
5. Apply etchant such as Zest's Sure Etch™ per manufacturer's instructions.

6. Apply bonding agent such as Zest’s Prelude™ or Prelude One™ per manufacturer’s instructions.
Note: ZNano Shade-Adaptive Universal Nanocomposite is compatible with a wide variety of methacrylate-based dental bonding primers and adhesives as well as etching techniques, including total-etch, self-etch and selective etch.

SHADE SELECTION AND PLACEMENT

1. To select a shade, using a Vita Classical Shade Guide compare the guide with a cleaned tooth, and select a ZNano Shade-Adaptive Universal Nanocomposite based on patient’s desired outcome.
2. Apply the selected color of ZNano Shade-Adaptive Universal Nanocomposite in layers that are each at a maximum of 2 mm thickness. Adapt and shape with an appropriate dental instrument. Light-cure afterwards.

Note: Successive layers will directly adhere as long as the oxygen layer is undisturbed.

LIGHT-CURING

1. Conventional polymerization devices are suitable for light-curing the material. The curing times are as follows when using an LED-/halogen light with a minimum light-output of 800mW/cm²:
 - 20 seconds for shades A1/B1, A2/B2 and A3/A3.5/B3
 - 40 seconds for C2/C3 and Bleach/Opaque (OM2)

Note: Hold the light emission tip of the device close to the surface of the filling. Other light sources or intensities than those described above require an adjustment to the cure time. See curing light manufacturer’s instructions.

FINISHING AND POLISHING





1. Complete restoration with preferred finishing and polishing steps.
2. Polish to a high gloss with discs or composite polishing points. Interproximal finishing/polishing is accomplished with fine grit finishing/polishing strips or a wheel.







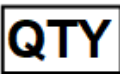

STORAGE

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

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, as defined in EU Directive 93/42/EEC	ISO 15223-1	5.1.1
	European Community Authorized Representative	Indicates the authorized representative in the European Community	ISO 15223-1	5.1.2
	Catalogue Number	Indicates the manufacturer’s catalogue number so that the medical device can be identified	ISO 15223-1	5.1.6
	Batch Code	Indicates the manufacturer’s batch code so that the batch or lot can be identified	ISO 15223-1	5.1.5

	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use	ISO 15223-1	5.4.3
	Use-by date	Indicates the date after which the medical device is not to be used	ISO 15223-1	5.1.4
	Upper Limit of Temperature	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1	5.3.6
	European Mark of Conformity	Indicates device is in conformance with Medical Device Directive 93/42/EEC	MDD 93/42/EEC	Annex XII
RxOnly	Rx Only	Caution: 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	ISO 15223-1	5.3.2
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	ISO 15223-1	5.4.2
	Quantity	Indicates the number of items within the package	N/A	N/A
	Medical device	Indicates the item is a medical device	DIS 15223-1 (2019)	5.7.7

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