

Paradigm™

Nano Hybrid Universal Restorative

ENGLISH

General Information

Paradigm™ Nano Hybrid Universal Restorative is a visible-light activated, radiopaque, restorative composite. It is designed for use in both anterior and posterior restorations. The filler in Paradigm Nano Hybrid Universal Restorative is a combination of surface modified zirconia/silica and 20 nm surface modified silica particles. The inorganic filler loading is 81.8% by weight, (67.8% by volume) with a particle size of 20 nm for the silica and approximately 0.1 - 10 microns for the zirconia/silica. Paradigm Nano Hybrid Universal Restorative contains BIS-GMA, UDMA, BIS-EMA, PEGDMA, and TEGDMA resins. A dental adhesive is used to permanently bond the restoration to the tooth structure.

Indications

Paradigm Nano Hybrid Universal Restorative is indicated for use in:

- Direct anterior and posterior restorations including occlusal surfaces
- Core Build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers

Precautionary Information for Patients

This product contains substances that may cause an allergic reaction by skin contact in 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 allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product.

Precautionary Information for Dental Personnel

This product contains substances that may cause an allergic reaction by skin contact in 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.

3M ESPE MSDS information can be obtained from www.3MESPE.com or contact your local subsidiary.

Instructions for Use

Preparation

1. **Prophy:** Teeth should be cleaned with pumice and water to remove surface stains.
2. **Shade Selection:** Before isolating the tooth, select the appropriate shade(s) of restorative material using a standard VITAPAN® Classic shade guide. Shade selection accuracy can be enhanced by the following hints.
 - 2.1. **Shade:** Teeth are not monochromatic. The tooth can be divided into three regions, each with a characteristic color.
 - 2.1.1. **Gingival area:** Restorations in the gingival area of the tooth will have various amounts of yellow.
 - 2.1.2. **Body area:** Restorations in the body of the tooth may consist of shades of gray, yellow, or brown.
 - 2.1.3. **Incisal area:** The incisal edges may contain a blue or gray color. Additionally, the translucency of this area and the extent of the translucent portion of the tooth to be restored and neighboring teeth should be matched.
 - 2.2. **Restoration depth:** The amount of color a restorative material exhibits is affected by its thickness. Shade matches should be taken from the portion of the shade guide most similar to the thickness of the restoration.
 - 2.3. **Mock-up:** Place the chosen shade of the restorative material on the unetched tooth. Manipulate the material to approximate the thickness and site of the restoration. Cure. Evaluate the shade match under different lighting sources. Remove the restoration material from the unetched tooth with an explorer. Repeat the process until an acceptable shade match is achieved.
3. **Isolation:** A rubber dam is the preferred method of isolation. Cotton rolls plus an evacuator can also be used.

Direct Restorations

1. **Cavity Preparation:**
 - 1.1. **Anterior restorations:** Use conventional cavity preparations for all Class III, IV and Class V restorations.

- 1.2. **Posterior restorations:** Prepare the cavity. Line and point angles should be rounded. No residual amalgam or other base material should be left in the internal form of the preparation that would interfere with light transmission and therefore, the hardening of the restorative material.
2. **Pulp Protection:** If a pulp exposure has occurred and if the situation warrants a direct pulp capping procedure, use a minimum amount of calcium hydroxide on the exposure followed by an application of 3M™ ESPE™ Vitrebond™ or Vitrebond Plus™ Light Cure Glass Ionomer Liner/Base. Vitrebond liner/base may also be used to line areas of deep cavity excavation. See Vitrebond liner/base instructions for details.
3. **Placement of Matrix:**
 - 3.1. **Anterior restorations:** Mylar strips and crown forms may be used to minimize the amount of material used.
 - 3.2. **Posterior restorations:** Place a thin dead-soft metal, or a precontoured-Mylar or a precontoured-metal matrix band and insert wedges firmly. Burnish the matrix band to establish proximal contour and contact area. Adapt the band to seal the gingival area to avoid overhangs.

Note: The matrix may be placed following the enamel etching and adhesive application steps if preferred.
4. **Adhesive System:** Follow the manufacturer's instructions regarding etching, priming, adhesive application and curing.
5. **Dispensing the Composite:** Follow the directions corresponding to the dispensing system chosen.
 - 5.1. **Syringe:** Dispense the necessary amount of restorative material from the syringe onto the mix pad by turning the handle slowly in a clockwise manner. To prevent oozing of the restorative material when dispensing is completed, turn the handle counterclockwise a half turn to stop paste flow. Immediately replace syringe cap. If not used immediately, the dispensed material should be protected from light.
 - 5.2. **Single-Dose Capsule:** Insert capsule into 3M ESPE Restorative Dispenser. Refer to separate restorative dispenser instructions for full instructions and precautions. Extrude restorative directly into cavity.
6. **Placement:**
 - 6.1. Place and light cure restorative in increments as indicated in Section 7.
 - 6.2. Slightly overfill the cavity to permit extension of composite beyond cavity margins. Contour and shape with appropriate composite instruments.
 - 6.3. Avoid intense light in the working field.
 - 6.4. Posterior placement hints:
 - 6.4.1. To aid in adaptation, the first 1 mm layer may be placed and adapted to the proximal box.
 - 6.4.2. A condensing instrument (or similar device) can be used to adapt the material to all of the internal cavity aspects.
7. **Curing:** Paradigm Nano Hybrid Universal Restorative is intended to be cured with a halogen or LED light with a minimum intensity of 400 mW/cm² in the 400-500 nm range. Cure each increment by exposing its entire surface to a high intensity visible light source, such as 3M ESPE curing light. Hold the light guide tip as close to the restorative as possible during light exposure. The recommended exposure time and maximum increment thickness for each shade is shown below.

Minimum intensity 400 mW/cm ² lights		
Shades	Incremental Depth	Cure Time
A1, A2, A3, A3.5, A4, B1, B2, B3, C2, D3	2.0 mm	20 sec.
OA2, OA3	1.5 mm	20 sec.
8. **Contouring:** Contour restoration surfaces with fine finishing diamonds, burs or stones. Contour proximal surfaces with 3M™ ESPE™ Sof-Lex™ Finishing Strips.

9. **Adjust Occlusion:** Check 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.
10. **Finishing and Polishing:** Polish with Sof-Lex™ Finishing and Polishing System and with white stones or rubber points where discs are not suitable.

Indirect Procedure for Inlays, Onlays or Veneers

1. Dental Operatory Procedure

- 1.1. **Shade selection:** Choose the appropriate shade(s) of Paradigm Nano Hybrid Universal Restorative prior to isolation. If the restoration is of sufficient depth, use of an opaque shade is recommended.
- 1.2. **Preparation:** Prepare the tooth.
- 1.3. **Impressioning:** After preparation is complete, make an impression of the prepared tooth by following the manufacturer's instructions of the impressioning material chosen. A 3M ESPE impressioning material may be used.

2. Laboratory Procedure

- 2.1. Pour the impression of the preparation with die stone. Place pins at the preparation site at this time if a "triple tray" type of impression was used. Then use the appropriate technique to achieve model work with removable sections that corresponds with the type of impression that is being used.
- 2.2. Separate the cast from the impression. Refer to stone manufacture for the appropriate set times before separating. Use the appropriate technique to achieve model work with removable sections that corresponds with the type of impression that was used. Mount or articulate the cast to its counter model using an adequate articulator.
- 2.3. If a second impression was not sent, pour a second cast using the same impression registration. This is to be used as a working cast.
- 2.4. Section out the preparation with a laboratory saw and trim away excess and expose the margins so they can be easily worked. Mark the margins with a red pencil if needed and harden the preparation with die hardener. Add a spacer at this time if one is being used.
- 2.5. Add the first third of composite to the floor of the preparation, stay short of the margins, light cure for 20 seconds.
- 2.6. Add the second third of composite. Allow for the last third (incisal) to include the contact areas, light cure for 20 seconds.
- 2.7. Place the die back into the articulated arch, add the last third of incisal composite to the occlusal surface. Overfill very slightly mesially, distally, and occlusally. This will allow for the mesiodistal contacts and the proper occlusal contact when the opposing arch is brought into occlusion with the uncured incisal increment. Light cure for only ten seconds, then remove the die to prevent adhering to adjacent surfaces. Finish the curing process.
- 2.8. With the occlusal contacts already established, begin removing the excess composite from around the points of contact. Develop the inclines and ridges as per remaining occlusal anatomy.
- 2.9. Care must be taken when removing the prosthesis from the die. Break off small amounts of the die from around the restoration, the die stone should breakaway cleanly from the cured restoration, until all of the restoration is recovered.
- 2.10. Using the master die, check the restoration for flash, undercuts, and fit (mesially, distally, and occlusally). Adjust as necessary, then polish.

3. Dental Operatory Procedure

- 3.1. Roughen the interior surfaces of the indirect restoration.
- 3.2. Clean the prosthesis in a soap solution in an ultrasonic bath and rinse thoroughly.
- 3.3. **Cementation:** Cement the prosthesis using a 3M ESPE resin cement system by following manufacturer's instructions.

Storage and Use

1. This product is designed to be used at room temperature. If stored in cooler, allow product to reach room temperature prior to use. Shelf life at room temperature is 36 months. Ambient temperatures routinely higher than 27°C/80°F may reduce shelf life. See outer package for expiration date.
2. Do not expose restorative materials to elevated temperatures or intense light.
3. Do not store materials in proximity to eugenol containing products.

Cleaning and Disinfection

Disinfect the 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.

Disposal

See the Material Safety Data Sheet (available at www.3MESPE.com) or through your local subsidiary) for disposal information.

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.

Warranty

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability

Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

			
Use By	Caution, see instructions for use	Storage	Do Not Reuse
Utiliser avant le	Précautions à prendre, consulter les directives d'utilisation	Entreposage	Ne pas réutiliser

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3M ESPE Customer Care/MSDS Information:
U.S.A. 1-800-634-2249 and Canada 1-888-363-3685.

3M ESPE

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