

# GRADIA® DIRECT

LIGHT-CURED COMPOSITE RESTORATIVE

For use only by a dental professional in the recommended indications.

## RECOMMENDED INDICATIONS

- A. GRADIA DIRECT ANTERIOR
  - Direct restorative for Class II, IV, V cavities.
  - Direct restorative for wedge-shaped defects and root surface cavities.
  - Direct restorative for veneers and diastema closure.
- B. GRADIA DIRECT POSTERIOR (radopaque)
  - Direct restorative for Class I and II cavities

## CONTRAINDICATIONS

1. In rare cases the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.

## DIRECTIONS FOR USE

1. Shade Selection  
For bonding GRADIA DIRECT to enamel and / or dentin, use a light-cured bonding system such as G-BOND®, G-genia® Bond (G-BOND®) (Fig. 1).
2. Placement of GRADIA DIRECT  
Follow manufacturer's instructions.
3. Insert the GRADIA DIRECT Unip® into the cavity. Press the application tip against the cavity and extrude material directly into the prepared cavity. Use steady pressure (Fig. 2). Maintain contact with the application tip and the Unip APPLIER and Unip from the mouth. This prevents the Unip from coming loose on the mixing pad.
4. Removing syringe cap and dispense material onto a mixing pad. Place the material into the cavity using a suitable placement instrument, such as the application plunger antiochocolor by a half to full turn to release residual pressure inside the syringe. Replace cap immediately after use.

5. Basicly, material can be applied in a single layer to achieve aesthetic restorations using Standard shades. For details, refer to the Clinical Hints.
6. Material may be hard to extrude immediately after removing from GC Fuji Lining®. In such cases, use a higher temperature of irradiation for a few minutes at normal room temperature.
7. After dispensing, avoid too long an exposure to ambient light.

## Clinical Hints

1. Anterior cavities  
In the case of small cavities, restore using a one shade layering technique. In most cases the use of one Standard shade alone will be sufficient. In cases where a higher degree of translucency is needed, one of the Outside special shades can be selected. See also Examples of Clinical Applications.
2. In the case of large cavities  
In most cases the use of layering technique will give the best aesthetic results. To block out shine throughs from the oral cavity or to mask discoloration of dentin, select an appropriate Inside special shade and continue to build up with a Standard shade.
3. To make a restoration more like life or to copy age related changes appearing on the final layer should consist of an Outside special shade. See also Examples of Clinical Applications and / or consult the Shade Combination Chart.

2. Posterior cavities  
In the case of small cavities, restore using a one shade layering technique. In most cases the use of one Standard shade alone will be sufficient. In cases where a higher translucency is needed, one of the Outside special shades is recommended. See also Examples of Clinical Applications.
3. In the case of deep cavities  
Place a flowable composite such as GRADIA DIRECT Flo or GRADIA DIRECT Loft® over the preparation, then apply a Standard shade. For optimal aesthetics use an Outside special shade as the final composite layer. See also Examples of Clinical Applications.

\*GC Fuji Lining® PASTE PAK, GC Fuji Lining® LC or GC Fuji IX can also be used as a liner or base material. Follow the respective instructions for use.

## Examples of Clinical Applications (Clinical Hint No. 1, 2)

	A1	A2	A3	A3.5	A4	B1	B2	B3	C3
Inside special	BW	A02	A03	A04	A4	B1	B2	B3	C3
Standard	A1	A2	A3	A3.5	A4	B1	B2	B3	C3
Outside special	WT	DT	DT	DT	DT	WT	WT	DT	DT

For details of shades, refer to the following section of SHADES.

5. Contouring before Light Curing  
Use the following standard techniques.
6. Light Curing  
Light cure GRADIA DIRECT using a light curing unit.

Refer to the following chart for Irradiation Time and Effective Depth of Cure.

GRADIA DIRECT ANTERIOR: Irradiation Time and Effective Depth of Cure		3 sec.	6 sec.
irradiation time	Plasma arc (2000mW/cm <sup>2</sup> )	10 sec.	20 sec.
	GC G-Light (1200mW/cm <sup>2</sup> )	20 sec.	40 sec.
Shade	Halgén / LED (700mW/cm <sup>2</sup> )	20 sec.	40 sec.
CT, NT, WT, GT, CVT		3.0 mm	3.5 mm
A1, A2, B1, B2, XBW, BW, DT		2.5 mm	3.0 mm
A3, B3		2.0 mm	3.0 mm
A3.5, A4, C3, A02, A03, A04, CV, CVD		1.5 mm	2.5 mm

GRADIA DIRECT ANTERIOR: Irradiation Time and Effective Depth of Cure		3 sec.	6 sec.
irradiation time	Plasma arc (2000mW/cm <sup>2</sup> )	10 sec.	20 sec.
	GC G-Light (1200mW/cm <sup>2</sup> )	20 sec.	40 sec.
Shade	Halgén / LED (700mW/cm <sup>2</sup> )	20 sec.	40 sec.
PA-1, PA-2, P-WT, P-NT		2.5 mm	3.0 mm
PA-3, PA-3.5		2.0 mm	3.0 mm

Note:  
1. Material should be placed and light cured in layers. For maximum layer thickness, please consult the tables.  
2. Lower intensity may cause insufficient curing or discoloration of the material.

7. Finishing and Polishing  
Finish and polish using diamond burs, polishing points and discs. To obtain a high gloss, polishing pastes can be used.

## Cleaning and Sterilizing of the Unip APPLIER

1. The Unip APPLIER should be cleaned with alcohol.
2. The applicator may be steam autoclaved at 121-135°C (250-275°F) for 10 to 30 minutes or disinfected using alcohol.

1. Do not attempt to sterilize in a unit at a temperature that exceeds 121°C during the drying step of the autoclave procedure. Otherwise, the applicator may be damaged.
- 2) The use of various chemical disinfectants / sterilants may cause material discoloration and therefore is not recommended.

## Use of the Shade Guide

The shade guide can be cleaned with water and mild soap. It should not be sterilized. The use of various chemical disinfectants / sterilants may cause damage to the shade guide.

7. Finishing and Polishing  
Finish and polish using diamond burs, polishing points and discs. To obtain a high gloss, polishing pastes can be used.

## SHADES

1. 22 shades for anteriors  
Standard/Farben: XBW (Extra Bleaching White), BW (Bleaching White), A1, A2, A3, A3.5, A4, B1, B2, B3, C3 (Cervical), CVT (Cervical Dark)

2. 6 Outside special shades: WT (White Translucent), DT (Dark Translucent), CT (Clear Translucent), NT (Natural Translucent), GT (Gray Translucent), CVT (Cervical Translucent)

3. 24 shades for posteriors  
Standard/Farben: P-A1, P-A2, P-A3, P-A3.5  
Outside special shade: P-WT (White Translucent), P-NT (Natural translucent)

A, B, C, A0 shades are based on Vita® / Shade.

## STORAGE

Recommended for optimal performance, store in a cool and dark place (4 - 25°C / 39.2 - 77.0°F) away from high temperatures or direct sunlight.

GRADIA DIRECT ANTERIOR - 3 years from date of manufacture  
GRADIA DIRECT POSTERIOR - 3 years from date of manufacture

## PACKAGES

1. Unipits  
1. INTRODUCTION KIT (35 Unipits (7 shades))  
- 35 tips (5 pcs each in 7 shades) (0.16ml per tip)  
(6 anterior shades: A2, A3, A3.5, A03, CV, CT)  
- Shade guide

2. REFILL  
- 16 x 20 tips (each in 14 shades) (0.16ml per tip)  
(8 anterior shades - A1, A2, A3, A3.5, A03, CV, NT, DT)  
(8 anterior shades - P-A1, P-A2, P-A3, P-A3.5, P-WT, P-NT)  
- Pack of 10 tips (each in 14 shades) (0.16ml per tip)  
(14 anterior shades - XBW, BW, A4, B1, B2, B3, C3, A02, A04, CVD, CT, WT, DT, GT, CVT)

3. Unip APPLIER, B. shade guide, c. Mixing pad (No.14B)

## CAUTION

1. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.
2. In case of contact with oral tissue or skin, remove immediately with cotton or a sponge soaked in alcohol. Flush with water.
3. In case of contact with eyes, flush immediately with water and seek medical attention.
4. Take care to avoid ingestion of the material.
5. Wear protective rubber gloves during operation to avoid direct contact with air inhibited resin layers in order to prevent possible sensitivity.
6. For infection control reasons, Unipits are for single use only.
7. Wear protective eye glasses during light curing.
8. When polishing the polymerized material, use a dust collector and wear a dust mask to avoid inhalation of cutting dust.
9. Do not mix with other similar products.
10. Avoid getting material on clothing.
11. In case of contact with unintended areas of tooth or prosthetic appliances, remove with instrument, sponge or cotton pellet before light curing.

Some products referenced in the present IFU may be classified as hazardous materials as GRADIA may hinder GRADIA DIRECT from setting.

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## CLEANING AND DISINFECTING

MULTI-USE DELIVERY SYSTEMS: To avoid cross-contamination, disinfect these devices regularly with appropriate disinfectants immediately after use despite device and label for deterioration. Discard device if damaged.

DO NOT IMMERGE. Thoroughly clean device to prevent drying and accumulation of contaminants.

Disinfect with a multi-level registered healthcare-grade infection control product according to regional/national guidelines.

Latest revised: 02/2016

# GRADIA® DIRECT

LICHTHÄRTENDES KOMPOSIT-RESTAURATIVMATERIAL

Zur Verwendung nur durch einen Zahnmediziner für die empfohlenen Indikationen.

## EMPHOELNE INDICATIONEN

- A. GRADIA DIRECT ANTERIOR
  - Direkte Restaurationen von Kavitäten der Klassen II, IV und V.
  - Direkte Restaurationen von keilförmigen Defekten und Wurzel-Überflächenkavitäten.
  - Direkte Restaurationen von Veneers und zum Diastemaverschluss.
- B. GRADIA DIRECT POSTERIOR (Radopak)

## KONTRAINDIKATIONEN

1. In seltenen Fällen kann das Produkt bei empfindlichen Personen auftreten. In einem solchen Fall die Verwendung des Materials sofort abbrechen und den Arzt aufsuchen.

## VERARBEITUNG

1. Farbauswahl  
Reinigen des Zahns mit geeignetem Mittel und Wasser. Die Restaurationen werden am besten bei getrocknetem Zahn erfolgen. Mit dem GRADIA DIRECT Shade Guide Kit die passenden GRADIA DIRECT-Farben auswählen.
2. Vorbereitung der Kavität  
Die Kavität wie gewohnt vorbereiten.
3. Aufbringen des Unip  
Zum Abdecken der Pulpa ein geeignetes Calcium-Hydroxyd-Präparat verwenden.

4. Ausrufen von GRADIA DIRECT  
Den Unip APPLIER einsetzen. Danach die Kavität mit dem Material gleichmäßig in die Kavität einbringen (Abb. 2). Beim Entfernen des Unip und des Appliers aus dem Mund diesen Dicht aufrechterhalten, dadurch wird verhindert, daß sich der Unip aus dem Applier löst.

5. Grundständig können ästhetisch anspruchsvolle Restaurationen mit den Standardfarben in der Einschiebetechnik erzielt werden.
2. Nach sehr kühler Lagerung kann es schwierig sein, das Material zu entnehmen.
3. Nach dem Auspressen sollte das Material nicht zu lange dem Halbleuchtlicht ausgesetzt werden, da sich dadurch die Verarbeitungszeit verringert.

## Klinische Hinweise

1. Kleinere Kavitäten  
Restauration mit der Einschiebetechnik. In den meisten Fällen ist die Verwendung eines Standardfarbes ausreichend. Wenn eine stärkere Transparenz erforderlich sein sollte, kann zusätzlich eine Outside-Spezialfarbe verwendet werden. S. a. die Beispiele bei "Klinische Anwendung".
2. Große Kavitäten  
Die beste ästhetische Ergebnis wird in den meisten Fällen mit einem Blockbau erreicht. Um ein durchsichtiges Ergebnis zu erzielen, wählen Sie eine Outside-Spezialfarbe vornehmlich vor dem Auftragen der weiteren Aufbau vorgenommen wird.

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## Examples of Clinical Applications (Clinical Hint No. 1, 2)

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3. In case of contact with eyes, flush immediately with water and seek medical attention.
4. Take care to avoid ingestion of the material.
5. Wear protective rubber gloves during operation to avoid direct contact with air inhibited resin layers in order to prevent possible sensitivity.
6. For infection control reasons, Unipits are for single use only.
7. Wear protective eye glasses during light curing.
8. When polishing the polymerized material, use a dust collector and wear a dust mask to avoid inhalation of cutting dust.
9. Do not mix with other similar products.
10. Avoid getting material on clothing.
11. In case of contact with unintended areas of tooth or prosthetic appliances, remove with instrument, sponge or cotton pellet before light curing.

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## CLEANING AND DISINFECTING

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Latest revised: 02/2016

# GRADIA® DIRECT

COMPOSITE DE RESTAURATION PHOTOPOLYMERISABLE

Ce produit est réservé à l'art dentaire selon les recommandations indiquées.

## INDICATIONS

- A. GRADIA DIRECT ANTERIOR
  - Restaurations directes pour cavités de Classes II, IV, V.
  - Restaurations directes pour défauts coniques et caries au collet.
  - Restaurations directes pour facettes et diastème.
- B. GRADIA DIRECT POSTERIEUR (radopaque)

## CONTRAINDICATIONS

1. Coiffage pulpaire.  
2. Dans certains cas ce produit peut entraîner des réactions chez certaines personnes. Si tel est le cas, ne plus utiliser ce produit et consulter un médecin.

## MODE D'EMPLOI

1. Sélection de la teinte  
Nettoyer la dent avec de la ponce et de l'eau. La sélection de la teinte doit se faire avant l'isolation de la dent. Sélectionner la teinte GRADIA DIRECT appropriée en vous référant au tableau GRADIA DIRECT.
2. Préparation de la cavité  
Préparer la cavité en utilisant les techniques standard.
3. Application du Unip  
Utiliser un coiffage pulpaire, utiliser un hydroxyde de calcium.

4. Traitement adhésif  
Pour coller GRADIA DIRECT à l'émail et / ou à la dentine, utiliser un système de collage photopolymérisable comme G-BOND®, G-genia® Bond ou G-Premio Bond (Fig. 1).
5. Application de GRADIA DIRECT  
Suivre les instructions du fabricant.
6. Mise en place du GRADIA DIRECT  
Insérer l'Unip® GRADIA DIRECT dans son applicateur ou équivalent. Retirer le capuchon et appliquer la pression constante (Fig. 2). Maintenir la pression constante pendant le retrait de l'Unip de la bouche et de l'applicateur. Cela pour éviter que l'Unip ne saisisse l'applicateur.

7. Érogation de la siringue  
Toggler le capuchon della siringa ed estrarre il materiale su uno strumento adatti. Dopo aver estratto il materiale, notare il pistone della siringa di mezzo giro o di un giro completo in senso orario per eliminare la pressione residua all'interno della siringa. Riappare il cappuccio subito dopo l'uso.

8. Notes  
1. En général, il matériau peut être appliqué en une seule couche pour obtenir, avec des teintes standard, une restauration esthétique. Pour plus de détails, se référer au paragraphe suivant.
2. Après un stockage dans un réfrigérateur, il peut être difficile de retirer le matériau de l'Unip. Dans ce cas le :  
- Placer le matériau dans un récipient à température ambiante pendant quelques minutes avant utilisation.
3. Après distribution, éviter une trop longue exposition à la lumière UV. La luce dell'ambiente peut raccourcir le temps de polymérisation.

## « Casus » cliniques

1. Cavités antérieures  
Dans le cas de petites cavités, restaurer en utilisant la technique monochrome. En général, une seule teinte standard sera suffisante. Dans le cas où un degré plus important de translucidité est souhaité, une des teintes spéciales Outside peut être choisie. Voir également « Exemples cliniques ».
2. Dans le cas de larges cavités  
Dans la plupart des cas et pour donner les meilleurs résultats esthétiques, la technique de stratification avec un effet de transparence dans la cavité orale peut être utilisée. Choisir une teinte spéciale Outside pour masquer la dentine sous-jacente, sélectionner une teinte spéciale Inside et continuer la restauration et continuer à stratifier avec un color Standard. Par faire en mode que un restaura sempre più naturale, ad esempio per riprodurre alcune variazioni estetiche dovute alla, lo strato finale dovrebbe essere realizzato con un colore speciale Outside. Consultare anche gli esempi di applicazioni cliniche e / o i Grafici delle combinazioni di colori.

2. Cavités postérieures  
Dans le cas de petites cavités, restaurer en utilisant la technique monochrome. En général, une seule teinte standard sera suffisante. Dans le cas où un degré plus important de translucidité est souhaité, une des teintes spéciales Outside peut être choisie. Voir également « Exemples » et « Applications cliniques ».
3. Dans le cas de grandes cavités  
Placer un composite fluide comme GRADIA DIRECT Flo ou GRADIA DIRECT Loft® sur le fond de la cavité, puis appliquer un color Standard. Pour obtenir des résultats esthétiques optimaux, utiliser une teinte spéciale Outside comme couche finale de composite. Voir également « Exemples » et « Applications cliniques ».

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## Exemples d'applications cliniques (Suggestions Clinique No. 1, 2)

	A1	A2	A3	A3.5	A4	B1	B2	B3	C3
Inside special	BW	A02	A03	A04	A4	B1	B2	B3	C3
Standard	A1	A2	A3	A3.5	A4	B1	B2	B3	C3
Outside special	WT	DT	DT	DT	DT	WT	WT	DT</	





