

GRADIA® DIRECT

LIGHT-CURED COMPOSITE RESTORATIVE

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

RECOMMENDED INDICATIONS

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

CONTRAINDICATIONS

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

DIRECTIONS FOR USE

1. Shade Selection
Clean the tooth surfaces with pumice and water. Shade selection should be made prior to isolation. Select the appropriate GRADIA DIRECT shade by referring to the GRADIA DIRECT shade guide.
2. Cavity preparation
Prepare cavity using standard techniques.
3. For pulp capping, use calcium hydroxide.
3. Bonding Treatment
For bonding GRADIA DIRECT to enamel and / or dentin, use a light-cured bonding system such as G-BOND®, G-aenial® Bond or G-Premio Bond (Fig. 1).

4. Placement of GRADIA DIRECT
Following from a Unit APPLIER, remove the cap and extrude material directly into the prepared cavity. Use applicator (Fig. 2). Maintain firm pressure on the applicator until the material is fully seated. Then use the Unit APPLY Squeeze and Unit from the mouth. This prevents the Unit from coming loose from the mixing pad.

5. Finishing
Remove syringe cap and dispense material onto an mixing pad. Place the material into the cavity using a suitable placement instrument, such as dispensing, screw syringe plunger antedecorative by a half to full turn to release residual pressure inside the syringe. Replace cap immediately after use.

6. Note:
1. Basically, material can be applied in a single layer to achieve aesthetic restorations using Standard shades. For details, refer to the Clinical Hints.

2. Material may be hard to extrude immediately after removing from curing syringe. Prior to use, leave to stand for a few minutes at normal room temperature.

3. After dispensing, avoid too long an exposure to ambient light. Ambient light can shorten the manipulation time.

[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 the case of a multi shade layering technique will give the best aesthetic results. To block out shine throughs from the oral cavity, a one Standard shade alone is sufficient. In cases where a higher translucency is needed, one of the Outside special shades can be selected. See also Examples of Clinical Applications.

3. To make a restoration more life like e.g. to copy age related changes in appearance, the final layer should consist of an Outside special shade. See also Examples of Clinical Applications and / or consult the Shade Combination Chart.

4. Posterior cavities
a. 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 can be selected. See also Examples of Clinical Applications.

5. In the case of deep cavities
Place a flexible composite such as GRADIA DIRECT Flo or GRADIA DIRECT LoFlo® (radioopaque) in the cavity first. Then place 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 manufacturer's instructions for use.

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

	Standard	(A1)	(A2)	A3	A3.5	A4	B1	B2	B3	C3
Inside special	BW	A02	A03	A03.5	A04	BW	A02	B1	B2	B3
Standard	A1	A2	A3	A3.5	A4	B1	B2	B3	C3	C4
Outside special	WT	DT	DT	DT	DT	WT	WT	WT	DT	DT

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

5. Contouring before Light Curing
Clean the tooth surfaces with pumice and water. Contouring should be made prior to isolation. Select the appropriate GRADIA DIRECT shade by referring to the GRADIA DIRECT shade guide.

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

Irradiation time	Plasma arc (2000mW/cm²)	3 sec.	6 sec.
GC G-Light (2000mW/cm²)	10 sec.	20 sec.	40 sec.
Shade	Halogen / LED (700mW/cm²)	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 POSTERIOR: Irradiation Time and Effective Depth of Cure

Irradiation time	Plasma arc (2000mW/cm²)	3 sec.	6 sec.
GC G-Light (2000mW/cm²)	10 sec.	20 sec.	40 sec.
Shade	Halogen / LED (700mW/cm²)	20 sec.	40 sec.

P.A1, P.A2, P-WT, P-NT	2.5 mm	3.0 mm
P.A3, P.A3.5	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. The lighter light intensity may cause insufficient curing or discoloration of the material.

3. Avoid tooth 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 Unit APPLIER

1. Clean the Unit APPLIER with gauze soaked in alcohol.

2. The applicer may be steam autoclaved at 121-135°C (250-275°F) for 10 to 30 minutes or disinfected using alcohol.

3. Do not attempt to sterilize in a unit at a temperature that exceeds 121°C during the drying step of the autoclave procedure.

4. Otherwise, the applicer may be damaged.

5. The use of various chemical disinfectants / sterilants may cause damage to applicer and therefore is not recommended.

Cleaning 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.

SHADES

- 22 shades for anteriors
Standard shades : XBW (Extra Bleaching White), BW (Bleaching White), A1, A2, A3, A3.5, A4, B1, B2, B3, C3, CV (Cervical), CVD (Cervical Dark)

- Outside special shade : A02, A03, A04
Outside special shades : WT (White Translucent), DT (Dark Translucent), CT (Clear Translucent), NT (Natural Translucent), GT (Gray Translucent), CVT (Cervical Translucent)

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

- A, B, C, A/O shades are based on Vita® * Shade.

* Vita® is a registered trademark of Vita Zahnfabrik, Bad Säckingen, Germany.

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. Units
1 - INTRODUCTION KIT
(35 Units in 7 shades)

2. Shading tips (5 tips each in 7 shades) (0.16ml, per tip)
(6 anterior shades : A2, A3, A3.5, A03, CV, CT)
- Shade guide

3. R-2ALL
(8 anterior shades (A1, A2, A3, A3.5, A4) (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, A1, B1, B2, B3, C3, A02, A04, CVD, CT, WT, GT, CVT)
Note:
- Weight per Unit: 0.24g for anterior tip, 0.28g for posterior tip

4. Unit APPLIER B - Shade guide c. Mixing pad (No.148)

II. Syntetiset

1. INTRODUCTION KIT
(7 syringes (each in 7 shades) (2.7ml, per syringe)
(6 anterior shades : A2, A3, A3.5, A03, CV, CT)
(1 posterior shade : P-A2)
Shade guide

2. Syringes (in 28 shades) (2.7ml, per syringe)
1 syringe per syringe : 4.0g for anterior syringe, 4.7g for posterior syringe
3. Option
- Shade guide
- Mixing pad (No.148)

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. Avoid contact with rubber gloves during operation to avoid direct contact with air inhibited resin layers in order to prevent possible sensitivity.

6. For infection control reasons, Units are for single use only. Wear protective eye glasses when light curing.

7. When polishing the polymerised material, use a dust collector and wear a dust mask to avoid inhalation of cutting dust.

8. Avoid getting material on clothing.

9. In case of contact with contaminated areas of tooth or prosthetic appliances, remove with instrument, sponge or cotton pellet before applying material on clothing.

10. Avoid getting GRADIA DIRECT in combination with eugenol containing materials as eugenol may hinder GRADIA DIRECT from setting.

Some products referenced in the present IFU may be classified as hazardous according to GHS. Always familiarize yourself with the safety data sheets available at: <http://www.georgroup.com>. They can also be obtained from your supplier.

CLEANING AND DISINFECTING:

MULTI-USE DELIVERY SYSTEMS: To avoid cross-contamination, this device requires this device requires disinfection immediately after use inspect 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 mid-level registered healthcare-grade infection control product according to regional/national guidelines.

Latest revised: /02/2016

GRADIA® DIRECT

LICHTHÄRTENDES KOMPOSIT-RESTAURATIONS-MATERIAL

Zur Verwendung nur durch einen Zahnmediziner für die empfohlenen Indikationen.

EMPFOHLENE INDIKATIONEN

- A. GRADIA DIRECT ANTERIOR
 - 1. Direkte Restaurationen von Kavitäten der Klassen II, IV und V.
2. Restaurationen von Kieferflächen Defekten und Wurzel-Überflächenkavitäten.
3. Direkte Restaurationen von Veneren und zum Diastemaverschluss.
- B. GRADIA DIRECT POSTERIOR (Röntgensichtbar)
 - 1. Direkte Restaurationen von Kavitäten der Klassen I und II.

KONTRAINDIKATIONEN

1. Nach dem Abdecken der Pulpa greignett!

2. In seltenen Fällen kann eine Sensibilisierung bei einigen Personen auftreten. In einem solchen Fall die Verwendung des Materials sofort dem behandelnden Arzt aufsuchen.

VERABREITUNG

1. Farbwahl
Reinigen des Zahns mit geeignetem Mittel und Wasser. Die Farbwahl sollte vor dem Isolieren des Zahns erfolgen. Mit dem GRADIA DIRECT Shade Guide Kit die passenden GRADIA DIRECT –Farbe auswählen.

2. Vorbereitung der Kavität
Die Kavität wie gewohnt vorbereiten.

3. Abdecken der Pulpa
Ein geeignetes Calcium-Hydroxyd-Präparat zum Abdecken der Pulpa ein geeignetes Calcium-Hydroxyd-Präparat verwenden.

4. Aufbringen von GRADIA DIRECT
1) Benutzen von GRADIA DIRECT in einem Unit : Den GRADIA DIRECT Unit in den Unit APPLIER einsetzen. Danach die Schutzkappe entfernen und das Material gleichmäßig in die Kavität einbringen (Abb. 2). Beim Entfernen des Units und des Appliers aus dem Mund diesen Druck aufrechterhalten , dadurch wird verhindert, daß sich der Unitp aus dem Applier löst.

- 2) Benutzen von GRADIA DIRECT in Spritzenform
Die Kappe der Spritze entfernen und Material auf einen Amnischblock ausbringen. Mit einem geeigneten Instrument das Material in die Kavität aufbringen. Nach dem Ausdrücken der Spritze zu verhindern. Unmittelbar nach Gebrauch mit der Kappe wieder verschließen.

3. A Grundständig können ästhetisch anspruchsvolle Restaurationen mit den Standardfarben in der Einschiebtechnik erzielt werden. Details hierzu finden Sie bei den klinischen Hinweisen.

2. Nach sehr kühler Lagerung kann es schwierig sein, das Material zu entnehmen.

3. Nach dem Auspressen sollte das Material nicht zu lange dem Umgebungsluft ausgesetzt werden, da sich dadurch die Verarbeitungszeit verringert.

[Klinische Hinweise]

1. In most cases a multi shade layering technique will give the best aesthetic results. To block out shine throughs from the oral cavity, a one Standard shade alone is 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
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3. To make a restoration more life like e.g. to copy age related changes in appearance, the final layer should consist of an Outside special shade. See also Examples of Clinical Applications and / or consult the Shade Combination Chart.

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4. Unit APPLIER B - Shade guide c. Mixing pad (No.148)

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7. When polishing the polymerised material, use a dust collector and wear a dust mask to avoid inhalation of cutting dust.

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9. In case of contact with contaminated areas of tooth or prosthetic appliances, remove with instrument, sponge or cotton pellet before applying material on clothing.

- 10.

