

Prior to use, carefully read the instructions for use. **EN**

GRADIA® DIRECT X

LIGHT-CURED COMPOSITE RESTORATIVE

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

RECOMMENDED INDICATIONS

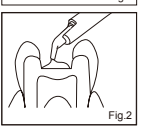
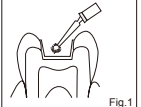
- Direct restorative for Class I, II, III, IV, V cavities.
- Direct restorative for wedge-shaped defects and root surface cavities.
- Direct restorative for veneers and diastema closure.

CONTRAINDICATIONS

- Pulp capping.
- Avoid use of this product in patients with known allergies to methacrylate monomer or methacrylate polymer.

DIRECTIONS FOR USE

- Shade Selection
Clean the tooth with pumice and water. Shade selection should be made prior to isolation. Select the appropriate GRADIA DIRECT X shades by referring to the chart.
- Cavity Preparation
Prepare cavity using standard techniques.
Note:
For pulp capping, use calcium hydroxide.
3. Bonding Treatment
For bonding GRADIA DIRECT X to enamel and / or dentin, use a light-cured bonding system such as GC-Premio BOND, G-aenial Bond, G-BOND or GC Fuji BOND LC (Fig. 1). Follow manufacturer's instructions.



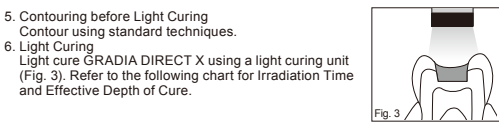
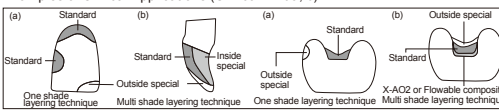
- Dispensing from a Unipit
Insert the GRADIA DIRECT X Unipit into the Unipit APPLIER II or equivalent. Remove the cap and extrude, screw syringe plunger anticlockwise to the prepared cavity. Use steady pressure (Fig. 2).
2. Maintain pressure on the applicator handle while removing the Unipit APPLIER II and Unipit from the mouth. This prevents the extruded material from being drawn back into the applicator.
3. Dispensing from a syringe
Remove syringe cap and dispense material onto a mixing pad.
Place the material into the cavity using a suitable placement instrument. After dispensing, screw syringe plunger anticlockwise by a half to full turn to release residual pressure inside the syringe. Replace cap immediately after use.
Note:

- The material can be applied in a single layer to achieve aesthetic restorations using Standard shades. For details, refer to the Clinical Hints.
- The material may be hand to extrude immediately after removing from cold storage. Prior to use, leave to stand for a few minutes at normal room temperature.
- The material can be applied in a single layer to achieve aesthetic restorations using Standard shades. For details, refer to the Clinical Hints.
- The material may be hand to extrude immediately after removing from cold storage. Prior to use, leave to stand for a few minutes at normal room temperature.

Clinical Hints

- In the case of small cavities
Restore using a one shade 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.
- In the case of large and/or deep cavities
In most cases a multi shade layering technique will give the best aesthetic results. To block out shine through from the oral cavity or to mask discolored dentin, place X-AO2 and continue to build up with a Standard shade. For optimal aesthetics use a Outside special shade as the final composite layer. In the case of deep posterior cavities, a flowable composite such as GRADIA DIRECT Fio /LoFo or a glass ionomer cement such as GC Fuji LINING LC (Paste Pak) or GC Fuji IX GP can be used on the cavity floor instead of an Opaque Shade. See also Examples of Clinical Applications.

Examples of Clinical Applications (Clinical Hint a, b)



5. Contouring before Light Curing
6. Light Curing
Use the GRADIA DIRECT X using a light curing unit (Fig. 3). Refer to the following chart for irradiation Time and Effective Depth of Cure.

Irradiation time	High power LED (more than 1200mW/cm²)		10 sec.	20 sec.
	Halogen /LED (700mW/cm²)			
X-A1, X-B1, X-WT	3.0 mm	3.5 mm		
X-A2, X-A3, X-B2, X-C2, X-D2	2.5 mm	3.0 mm		
X-A3.5, X-AO2, X-XBW, X-BW	2.0 mm	3.0 mm		

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

Cleaning and Sterilizing of the Unipit APPLIER II
Please refer to the Manufacturer's Instructions for Use for Cleaning and Sterilization of the Unipit APPLIER II.

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
Standard shade: X-XBW*, X-BW*, X-A1, X-A2, X-A3, X-A3.5, X-B1*, X-B2*, X-C2*, X-D2*
Inside special shade: X-AO2
Outside special shade: X-WT
*Not available in Europe.
Note:
A, B, C, D, AO 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. (Shelf life: 3 years from date of manufacture)

PACKAGES
I. Unipits
1. Pack of 20 tips (each in 5 shades) (0.16mL per tip)
X-A1, X-A2, X-A3, X-A3.5, X-WT
2. Pack of 10 tips (each in 7 shades) (0.16mL per tip)
X-XBW, X-BW, X-B1, X-B2, X-C2, X-D2, X-AO2
Note:
Weight per Unipit: 0.30g
3. Option
a. Unipit APPLIER II b. Shade guide c. Mixing pad (No.14B)
II. Syringes
1. 1 syringe (in 12 shades) (2.7mL per syringe)
Note:
Weight per syringe: 5.0g
2. Option
a. Shade guide b. Mixing pad (No.14B)
Note:
All packaging types may not be available in all countries.

CAUTION
1. In case of contact with oral tissue or skin, remove immediately with cotton or a sponge soaked in alcohol. Flush with water.
2. In case of contact with eyes, flush immediately with water and seek medical attention.
3. Take care to avoid ingestion of the material.
4. Prior to starting the filling process, partially extrude paste outside of the patient's mouth and away from the patient to ensure paste is flowing properly.
5. Wear plastic or 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 eyeglasses 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.
12. Do not use GRADIA DIRECT X in combination with eugenol containing materials as eugenol may hinder GRADIA DIRECT X from setting.
13. 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.
14. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.
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.gecorepo.com>
or for The Americas:
<http://www.gcamerica.com>
They can also be obtained from your supplier.

CLEANING AND DISINFECTING:
MULTI-USE DELIVERY SYSTEMS: to avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect device and label for deterioration. Discard device if damaged.
NO SUMMERGE: 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.

Last revised: 11/2017

MANUFACTURED BY
GC DENTAL PRODUCTS CORP.
2-285 Toritama-cho, Kaavagi, Aichi 486-0844, Japan
RESIN MANUFACTURER/STRENGTHENER IN CANADA:
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Vor der Benutzung bitte die Gebrauchsanweisung gründlich lesen! **DE**

GRADIA® DIRECT X

LICHTHÄRTENDES KOMPOSIT-RESTAURATIONS-MATERIAL

Zur Verwendung nur durch einen Zahnmediziner für die empfohlenen Indikationen.

EMPFLEHENE INDIKATIONEN

- Direkte Füllung für Klasse I, II, III, IV, V Kavitäten.
- Direkte Restaurationen direkt für keilförmigen Defekten und Wurzel-Oberflächenkavitäten.
- Direkte Restaurationen von Veneers und zum Diastemaverschluss.

KONTRAINDIKATIONEN

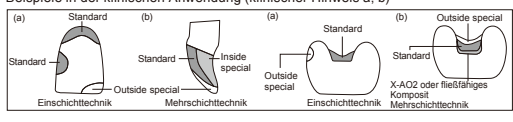
- Nicht zum Abdecken der Pulpa geeignet!
- Dieses Produkt darf nicht an Patienten verwendet werden, die eine Allergie gegen Methylacrylatmonomer oder Methylacrylatpolymer haben.

VERARBEITUNG

- Farbwahl
Reinigen des Zahns mit geeignetem Mittel und Wasser. Die Farbauswahl sollte vor dem Gebrauch erfolgen! Mit dem GRADIA DIRECT X Shade Guide Kit die passenden GRADIA DIRECT X –Farbe auswählen.
2. Vorbereitung der Kavität
Die Kavität wie gewohnt vorbereiten.
3. Bondung
Zum Abdecken der Pulpa ein geeignetes Calcium-Hydroxyd-Präparat verwenden.
4. Bondung
Für die Haftvermittlung zwischen GRADIA DIRECT X und dem Dentin / Zahnschmelz, ein lichthärtendes Haftvermittlungssystem wie G-Premio BOND, G-aenial Bond, G-BOND oder GC Fuji BOND LC verwenden (Abb. 1).
5. Dispensing from a Unipit
1) Benutzung von GRADIA DIRECT X in einem Unipit : Den GRADIA DIRECT X Unipit in den Unipit APPLIER II einsetzen. Danach die Schutzkappe entfernen und das Material gleichmäßig in die Kavität einbringen (Abb. 2). Beim Entfernen des Unipit und des Appliers aus dem Mund diesen Druck aufrechterhalten : dadurch wird verhindert, daß sich der Unipit aus dem Applier löst.
2) Benutzung von GRADIA DIRECT X 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 den Drehkolben entgegen dem Uhrzeigersinn eine halbe bis eine ganze Umdrehung drehen, um ein weiteres Ausstreuen von Material aus der Spritze zu verhindern. Unmittelbar nach Gebrauch mit der Kappe wieder verschließen.
6. Anm.:
1. Können ästhetisch anspruchsvolle Restaurationen mit den Standardfarben in der Einsichtstechnik erzielt werden. Details hierzu zu finden Sie bei den klinischen Hinweisen.
2. Nach sehr kühler Lagerung kann es schwierig sein, das Material zu entnehmen. Vor der Benutzung daher einige Minuten bei Raumtemperatur aufweichen!
3. Nach dem Auspressen sollte das Material nicht zu lange dem Umgebungslicht ausgesetzt werden, da sich hierdurch die Verarbeitungszeit verringert.

- In the case of small cavities
Restore using a one shade 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.
- In the case of large and/or deep cavities
In most cases a multi shade layering technique will give the best aesthetic results. To block out shine through from the oral cavity or to mask discolored dentin, place X-AO2 and continue to build up with a Standard shade. For optimal aesthetics use a Outside special shade as the final composite layer. In the case of deep posterior cavities, a flowable composite such as GRADIA DIRECT Fio /LoFo or a glass ionomer cement such as GC Fuji LINING LC (Paste Pak) or GC Fuji IX GP can be used on the cavity floor instead of an Opaque Shade. See also Examples of Clinical Applications.

Examples of Clinical Applications (Clinical Hint a, b)



5. Contourage avant photopolymérisation
6. Photopolymérisation
Photopolymériser GRADIA DIRECT X avec une unité de photopolymérisation (Fig. 3). Se référer au tableau des temps d'irradiation et des profondeurs de polymérisation.

5. Formung vor dem Licht härten
6. Licht härten
Licht härten GRADIA DIRECT X erfolgt mit einem Licht härten gerät (Abb. 3).

5. Contouring before Light Curing
6. Light Curing
Use the GRADIA DIRECT X using a light curing unit (Fig. 3). Refer to the following chart for irradiation Time and Effective Depth of Cure.

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Cleaning of the Shade Guide
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Standard shade: X-XBW*, X-BW*, X-A1, X-A2, X-A3, X-A3.5, X-B1*, X-B2*, X-C2*, X-D2*
Inside special shade: X-AO2
Outside special shade: X-WT
*Not available in Europe.
Note:
A, B, C, D, AO shades are based on Vita® Shade.
*Vita® is a registered trademark of Vita Zahnfabrik, Bad Säckingen, Germany.

STORAGE
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Note:
Weight per Unipit: 0.30g
3. Option
a. Unipit APPLIER II b. Shade guide c. Mixing pad (No.14B)
II. Syringes
1. 1 syringe (in 12 shades) (2.7mL per syringe)
Note:
Weight per syringe: 5.0g
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CAUTION
1. In case of contact with oral tissue or skin, remove immediately with cotton or a sponge soaked in alcohol. Flush with water.
2. In case of contact with eyes, flush immediately with water and seek medical attention.
3. Take care to avoid ingestion of the material.
4. Prior to starting the filling process, partially extrude paste outside of the patient's mouth and away from the patient to ensure paste is flowing properly.
5. Wear plastic or 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 eyeglasses 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.
12. Do not use GRADIA DIRECT X in combination with eugenol containing materials as eugenol may hinder GRADIA DIRECT X from setting.
13. 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.
14. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.
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.gecorepo.com>
or for The Americas:
<http://www.gcamerica.com>
They can also be obtained from your supplier.

CLEANING AND DISINFECTING:
MULTI-USE DELIVERY SYSTEMS: to avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect device and label for deterioration. Discard device if damaged.
NO SUMMERGE: 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.

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