

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

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

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 GRADIA DIRECT shade guide.

Cavity Preparation
Prepare cavity using standard techniques. Dry by gently blowing with oil free air.

Bonding Treatment
For bonding GRADIA DIRECT X to enamel and / or dentin, use a light-cured bonding system such as GC Fuji BOND LC, GC UniFil® Bond or GC G-BOND™ (Fig. 1). Follow manufacturer's instructions.

Placement of GRADIA DIRECT X

- Dispensing from a Unitip
Insert the GRADIA DIRECT X Unitip into the Unitip APPLIER or equivalent. Remove the cap and extrude material directly into the prepared cavity. Use steady pressure (Fig. 2). Maintain pressure on the applicator handle while moving the Unitip APPLIER and Unitip from the tooth. This prevents the Unitip from coming loose from the applicator.

- Dispensing from a syringe
Remove syringe cap and dispense material onto a mixing pad. Place the material into the cavity using the same placement instructions. After dispensing, screw syringe plunger antilockways by a half to full turn to release residual pressure inside the syringe. Replace cap immediately after use.

Note:

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

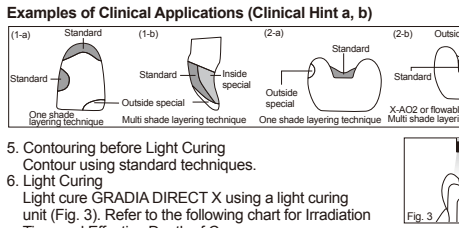
After dispensing, avoid too long an exposure to ambient light. Ambient light can shorten the manipulation time.

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 shade through from the oral cavity or to mask discolored dentine, place X-A2 and continue to build up with a Standard shade. For optimal aesthetic results, use an Outside special shade as the composite layer. In the case of deep posterior cavities, a flowable composite such as GC GRADIA DIRECT Flo / Loflo 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 Oraque shade. See also Examples of Clinical Applications.

Examples of Clinical Applications (Clinical Hint a, b)



Contouring before Light Curing
Contour using standard techniques.

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

GRADIA DIRECT X : Irradiation Time and Effective Depth of Cure

X-A2, X-A3, X-B2, X-C2, X-D2	2.5 mm	3.0
X-A3.5, X-AO2, X-XBW, X-BW	2.0 mm	3.0

Note :

1. Material should be placed and light cured in layers. For maximum

Shade 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-A3.5, X-B2, X-W, X-BW 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 light intensity may cause insufficient curing or discoloration of the material.

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

Cleaning and Sterilizing of the Unitip APPLIER

1. Clean the applicator with gauze soaked in alcohol.

2. The applicator may be steam autoclaved at 121-135°C (250-275°F) for 10 to 30 minutes if disinfection is required.

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. If sterilization is not recommended.

SHADES

Standard shade : X-BW, X-BW, X-A1, X-A2, X-A3, X-A3.5, X-B1, X-B2, X-C2, X-D2

Inside special shade : X-A2

Outside special shade : X-WT

A, B, C, D, AO shades are based on Vita® Shade.

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

PACKAGES

1. Pack of 20 tips (each in 5 shades) (0.16ml, per tip)

X-A1, X-A2, X-A3, X-A3.5, X-WT

1. Pack of 10 tips (each in 7 shades) (0.16ml, per tip)

X-BW, X-BW, X-B1, X-B2, X-C2, X-D2, X-A2

Note:

Weight per Unitip : 0.30g

Option

a. Unitip APPLIER b. Shade guide c. Mixing pad (No.148)

Syringes

1. syringe (in 12 shades) (2.7ml, per syringe)

Note:

Weight per syringe : 5.0g

Option

a. Shade guide b. Mixing pad (No.148)

CAUTION

In case of contact with oral tissue or skin, remove immediately with cotton or a sponge soaked in alcohol. Flush with water. To avoid contact, a rubber dam and/or cocoa butter is used to isolate the operation field from the skin or oral tissue.

In case of contact with eyes, flush immediately with water and seek medical attention.

Do not mix with other similar products.

Always wearing mask on clothing.

Do not use GRADIA DIRECT X in combination with eugenol containing materials as eugenol may hinder GRADIA DIRECT X from setting.

Last revised : 04/2010

CE 0086

MANUFACTURED BY

GC DENTAL PRODUCTS CORP.

23810 Tomimachi-cho, Kasuga, Aichi 466-0841, Japan

DISTRIBUTED BY

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GRADIA® DIRECT X

ФОТО-ПОЛИМЕРИЗИРАЦІЙ ВІЗНАВЛЕНИЙ КОМПОНІТ

За використання має со стоматологом за пропонуваннями індикаціями.

ПРОПОРАЧЕНІ ІНДИКАЦІЇ

- Директнй виставляння на квітвині ді І, ІІ, ІІІ, ІV, V клас.
- Директнй виставляння на квітвині дефекти і квітвети по кривоватій поверхні.
- Директнй виставляння – фасети і затваряння на диастемах.

КОНТРАІНДИКАЦІЇ

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

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 GRADIA DIRECT shade guide.

Cavity Preparation
Prepare cavity using standard techniques. Dry by gently blowing with oil free air.

Bonding Treatment
For bonding GRADIA DIRECT X to enamel and / or dentin, use a light-cured bonding system such as GC Fuji BOND LC, GC UniFil® Bond or GC G-BOND™ (Fig. 1). Follow manufacturer's instructions.

Placement of GRADIA DIRECT X

- Dispensing from a Unitip
Insert the GRADIA DIRECT X Unitip into the Unitip APPLIER or equivalent. Remove the cap and extrude material directly into the prepared cavity. Use steady pressure (Fig. 2). Maintain pressure on the applicator handle while moving the Unitip APPLIER and Unitip from the tooth. This prevents the Unitip from coming loose from the applicator.

- Dispensing from a syringe
Remove syringe cap and dispense material onto a mixing pad. Place the material into the cavity using the same placement instructions. After dispensing, screw syringe plunger antilockways by a half to full turn to release residual pressure inside the syringe. Replace cap immediately after use.

Note:

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

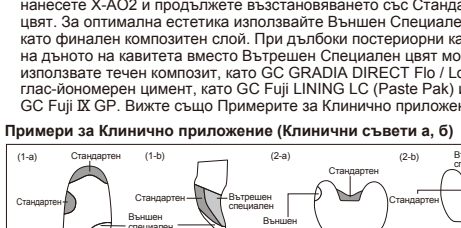
After dispensing, avoid too long an exposure to ambient light. Ambient light can shorten the manipulation time.

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 shade through from the oral cavity or to mask discolored dentine, place X-A2 and continue to build up with a Standard shade. For optimal aesthetic results, use an Outside special shade as the composite layer. In the case of deep posterior cavities, a flowable composite such as GC GRADIA DIRECT Flo / Loflo 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 Oraque shade. See also Examples of Clinical Applications.

Examples of Clinical Applications (Clinical Hint a, b)



Contouring before Light Curing
Contour using standard techniques.

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

GRADIA DIRECT X : Irradiation Time and Effective Depth of Cure

Време	Плазмена лъча (200mW/cm²)	3 sec.	6 sec.
GC Light (1200mW/cm²)	10 sec.	20 sec.	
Halogen / LED (700mW/cm²)	20 sec.	40 sec.	

Shade 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-A3.5, X-B2, X-W, X-BW 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 light intensity may cause insufficient curing or discoloration of the material.

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

Cleaning and Sterilizing of the Unitip APPLIER

1. Clean the applicator with gauze soaked in alcohol.

2. The applicator may be steam autoclaved at 121-135°C (250-275°F) for 10 to 30 minutes if disinfection is required.

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. If sterilization is not recommended.

SHADES

Standard shade : X-BW, X-BW, X-A1, X-A2, X-A3, X-A3.5, X-B1, X-B2, X-C2, X-D2

Inside special shade : X-A2

Outside special shade : X-WT

A, B, C, D, AO shades are based on Vita® Shade.

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PACKAGES

1. Pack of 20 tips (each in 5 shades) (0.16ml, per tip)

X-A1, X-A2, X-A3, X-A3.5, X-WT

1. Pack of 10 tips (each in 7 shades) (0.16ml, per tip)

X-BW, X-BW, X-B1, X-B2, X-C2, X-D2, X-A2

Note:

Weight per Unitip : 0.30g

Option

a. Unitip APPLIER b. Shade guide c. Mixing pad (No.148)

Syringes

1. syringe (in 12 shades) (2.7ml, per syringe)

Note:

Weight per syringe : 5.0g

Option

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CAUTION

In case of contact with oral tissue or skin, remove immediately with cotton or a sponge soaked in alcohol. Flush with water. To avoid contact, a rubber dam and/or cocoa butter is used to isolate the operation field from the skin or oral tissue.

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Do not mix with other similar products.

Always wearing mask on clothing.

Do not use GRADIA DIRECT X in combination with eugenol containing materials as eugenol may hinder GRADIA DIRECT X from setting.

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GRADIA® DIRECT X

SVĚTLEM TĚNUJÍCÍ KOMPOZITNÍ VÝPLŇOVÝ MATERIÁL

K použití pouze ve stomatologické praxi v doporučených indikacích.

DOPORUČENÉ INDIKACE

- Primární výplňový materiál pro kavitativní třídy I, II, III, IV, V třídy.
- Direktní opravy po kinnatě odělení a kavitativní povrchové koronky.
- Primární výplňový materiál na řezáky a zatvarování diastem.

KONTRAINDIKACE

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

NÁVOD K POUŽITÍ

Výběr odstínu
Zub očistěte pempou a vodou. Odstín by měl být vybrán před izolací zubu. Připravte izolovaný zub GRADIA DIRECT X vyberte podle vzorníku GRADIA DIRECT X.

Příprava kavit
Připravte kavitaci obvyklým postupem. Lehce osušte vzduchovou stříkačkou bez přísady oleje.

Applikace
K bondování GRADIA DIRECT X ke sklovině anebo dentinu použijte lepidlo GC Fuji BOND LC, GC UniFil® Bond nebo GC G-BOND™ (viz 1). Dodržte pokyny výrobce.

Umístění GRADIA DIRECT X

- 1) Aplikace z Unitipu
Koncovku Unitip GRADIA DIRECT X nasadte do Unitip APPLIER nebo ekvivalentu. Odstraňte krycí víčko a extrudujte materiál přímo do připravené kavitace. Používejte tlak (viz 2). Udržujte tlak na aplikátoru, zatímco přesouváte aplikátor a Unitip od zubu. Toto zabrání Unitipu od vytržení z aplikátoru.

- 2) Aplikace z tuby
Odstraňte krycí víčko a extrudujte materiál přímo do připravené kavitace. Používejte tlak (viz 2). Udržujte tlak na aplikátoru, zatímco přesouváte aplikátor a Unitip od zubu. Toto zabrání Unitipu od vytržení z aplikátoru.

Note:

- Basically, material can be applied in a single layer to achieve aesthetic restorations using Standard shades. For details, refer to the Clinical Hint.
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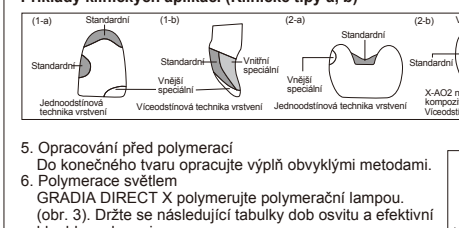
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Examples of Clinical Applications (Clinical Hint a, b)



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Contour using standard techniques.

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Light cure GRADIA DIRECT X using a light curing unit (Fig. 3). Refer to the following chart for irradiation Time and Effective Depth of Cure.

GRADIA DIRECT X : Irradiation Time and Effective Depth of Cure

X-A2, X-A3, X-B2, X-C2, X-D2	2,5 mm	3
X-A3.5, X-AO2, X-XBW, X-BW	2,0 mm	3

Poznámka:
1. Materiál sa nanáša a polymeruje vo vrstvách. Údaje o max

Shade 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-A3.5, X-B2, X-W, X-BW 2.0 mm 3.0 mm

Note:

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SHADES

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Inside special shade : X-A2

Outside special shade : X-WT

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X-A1, X-A2, X-A3, X-A3.5, X-WT

1. Pack of 10 tips (each in 7 shades) (0.16ml, per tip)

X-BW, X-BW, X-B1, X-B2, X-C2, X-D2, X-A2

Note:

Weight per Unitip : 0.30g

Option

a. Unitip APPLIER b. Shade guide c. Mixing pad (No.148)

Syringes

1. syringe (in 12 shades) (2.7ml, per syringe)

Note:

Weight per syringe : 5.0g

Option

a. Shade guide b. Mixing pad (No.148)

CAUTION

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