GC GRADIA® PREMi

Prior to use, carefully read the instructions for use.

3D PRINTABLE LIGHT-CURED COMPOSITE FOR DEFINITIVE DENTAL RESTORATIONS

DESCRIPTION
GC GRADIA PREMi is an alternative to traditional dental prosthetic material that is intended exclusively for professional dental work. The device is conjunction with a SprintRay MIDAS 3D printer. It is available in the following shades: A1, A2, A3, B1. The compressive strength is 370 MPa. The flexural strength is 170 MPa. The biaxial strength is 220 MPa. The material has a radiopacity equivalent to 2.5-3.0 mm of aluminium (dentin = 1 mm, enamel = 2 mm) . The particle size of inorganic fillers range is 0.02-1.3 µm.

PRINTING AND HARDWARE PARAMETERS
The device specifications have been only validated using the SprintRay MIDAS 3D printer and RayWare Cloud.
• Printer: SprintRay MIDAS 3D printer
  i. MIDAS: 45-micron XY resolution and power of 29 mW/cm^2
• Software: RayWare Cloud
  i. STL file import
  ii. Automatic or manual orientation
• Printing Parameters
  i. MIDAS: Automatically oriented on RayWare Cloud
  ii. Default layer thickness (100 microns)
  iii. Default support structures

INTENDED PURPOSE
Indirect permanent restoration of anterior and posterior teeth.

INDICATIONS FOR USE
• Individual and fixed definitive full single crowns
• Definitive partial crowns in anterior and posterior area
• Individual and fixed single veneers

CLINICAL BENEFIT
1. Permanent restoration of masticatory function.
2. Improvement of the teeth aesthetics.

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

INTENDED USERS/SPECIAL TRAINING
- Dentists
- Dental technicians
- No special training required

PATIENT TARGET GROUP
Patients needing to restore missing or damaged tooth tissue in anterior and posterior teeth.

COMPOSITION
Barium glass (60-70%), dimethacrylate (25-35%), silicon dioxide (1-5%), initiator (trace), pigment (trace), stabilizer (trace)

PERFORMANCE CHARACTERISTICS
The product's performance characteristics satisfy the requirements of the intended use.

DIRECTION FOR USE
Manufacturing Process for Dental Restorations

PREPARATION DESIGN
The restoration is designed using dental CAD software based on the patient's digital anatomical data and exported as an STL file. This STL file is delivered to the dental professional for fabrication. The STL file is then used for fabrication of the restoration.

PRINTING
Follow the instructions for priming the capsule before scanning and placing it on the MIDAS printer. For detailed priming instructions refer to the Workflow Guide. Failure to properly prime the capsule may lead to printing failure.
1. Identify the capsule cylinders, then turn upside down.
2. Press the white cylinder halfway down.
3. Press the black cylinder all the way down.
4. Repeat step 2 and 3 at least 10 times to fully prime.

Printing on MIDAS: Navigate to the Queue and select your print job. Follow the on-screen prompts to start the print.
NOTE:
At storage at low temperatures, such as during winter or in refrigeration, allow the product to stand at room temperature for a few hours before use.

CLEANING OF PRINTED OBJECTS
After your device has been printed, remove it from the print platform using the provided Print Removal Tool. Remove all supports using a flush cutter or round diamond disc. Cut as close as possible to the device to minimize the smoothing and finishing procedure.
i. Wipe off excess resin with an IPA-soaked towel*
ii. Blow air onto the appliance until the surface is IPA free
iii. With an IPA-soaked towel*, wipe the surface of the appliance until the surface is visually resin free.
iv. Blow the appliance with dry air for at least 30 seconds to "fully dry" the surface before post curing. This step ensures all residual alcohol is removed from the appliances.

*It is recommended to use the 91% or higher IPA.

POST CURING
Printed on MIDAS: use the following post-curing equipment and processes. For GC GRADIA PREMi devices, use the recommended settings:
• NanoCure (preprogrammed material profile)

FINISHING AND POLISHING
Finish and polish with coarse and fine silicone point. DIAPOLISHER PASTE can be used for final polishing to obtain high gloss.

CEMENTATION
With Sandblasting technique:
1) Sandblasting with 25-50 µm alumina 0.20 MPa/2.0 bar is recommended.
2) Blow the restoration with an oil-free air syringe or clean with an ultrasonic cleaner and dry.
3) Clean with alcohol to remove oil residue.
4) Treat the surface with a silane coupling agent such as G-Multi PRIMER.
5) Cement with an adhesive resin cement such as G-CEM ONE.

With hydrofluoric acid etching:
1) Treat with hydrofluoric acid (5%) for 60 seconds.
2) Wash with water spray or an ultrasonic cleaner and dry.
3) Treat the surface with a silane coupling agent such as G-Multi PRIMER.
4) Cement with an adhesive resin cement such as G-CEM ONE.

ADDITIONAL APPLICATION AND REPAIR
Roughen the bonding area using diamond point or carbide bur. Apply G-Multi PRIMER to improve adhesion and dry the surface. Apply a bonding agent following its manufacturer's instruction. Proceed with the application of the chosen composite restorative material. G-ænial Universal Flo or G-ænial Universal Injectable is recommended in order to make the surface of restorative homogeneous as it consists of the same flexible nano ceramic technology as GC GRADIA PREMi. In this case, the intermediate use of a bonding agent is not necessary.

CHARACTERIZATION
When appropriate, OPTIGLAZE color or GRADIA PLUS Lustre Paint is recommended as surface characterization and glazing technique. Sandblast with 25-50 µm alumina (0.20 MPa/2.0 bar.), clean and dry. Apply G-Multi PRIMER, dry and apply OPTIGLAZE color or GRADIA PLUS Lustre Paint. OPTIGLAZE color and GRADIA PLUS Lustre Paint can only be cured with a light-curing device with light source having wavelength lower than 430 nm. Refer to the respective instructions for use.

DISPOSAL
Dispose of all waste according to local regulations.

STORAGE
Recommended for optimal performance, store in a cool and dark place (4-25°C /39-77°F).

SIDE EFFECTS
There are no known side effects to date.

RESIDUAL RISKS
Gingival inflammation.

PRECAUTIONS, WARNINGS AND LIMITATIONS OF USE
Do not use if the prescribed application technique cannot be applied.
1. In case of contact with eyes, flush immediately with water and seek medical attention.
2. Do not use in cases with a high risk of fracture, such as those accompanied by malocclusion or bruxism.
3. Personal Protective Equipment (PPE) such as gloves, face masks and safety eyewear should always be worn. Wearing gloves during use avoids direct contact with unpolymerized resin in order to prevent possible sensitivity. Refer always to Safety Data Sheets (SDS).
4. When polishing polymerized material, use a dust collector and wear a dust mask to avoid inhalation of cutting dust.
5. Avoid getting material on clothing.
6. Capsules are for single use only.
7. Discard left over items (material cannot be reused).

Some products referenced in this Instructions for Use may be classified as hazardous according to GHS. Always familiarize yourself with the Safety Data Sheets available at:
https://www.gc.dental/america/resources-and-ifu
They can also be obtained from your supplier.

SHADE
A1, A2, A3, B1

NOTE:
The current Instructions for Use are available at https://www.gc.dental/america/resources-and-ifu.

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℞ Only

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