CAD/CAM BLOCK

T-BLOCK/C-BLOCK/i-BLOCK

USA

DENTISTRY

Instruction for use

Important notes

Read these instructions for use carefully before each use and keep them easily accessible for the user or the relevant technical personnel.

Carefully read the warnings indicated by this symbol. Improper use of the products may result in serious injury to the patient, users or third parties.

Rx only May only be supplied to dentists and dental laboratories or on their behalf. Keep away from children! Only for use by dentists!

REF The instructions for use are valid for CAD/CAM blocks with the following article numbers: 191XX, 191XX.A, 191XXA.L, 211XX

Product description

The uniqueness of the edelweiss CAD/CAM BLOCK lies in the manufacturing process, in which a hybrid glass block is produced by the patented process of vitrification and laser sintering. As a result, the edelweiss CAD/CAM BLOCK combines the properties of the current CAD/CAM systems in a single block. It has properties comparable to those of feldspar glass-ceramics.

Intended use

The edelweiss CAD/CAM BLOCK is used for the fabrication of indirect single-tooth restorations using CAD/CAM technology.

Indications for use

The T-BLOCK and C-BLOCK are used for the following indications:
- Crowns, inlays, onlays and veneers
- Implant-supported crowns

The i-BLOCK is used for the following indication:
- Implant-supported crowns

Contraindications

Contraindicated in the case of any hypersensitivity or allergy to any of the ingredients.

Side effects

No systemic side effects are known. Contact allergies with products of similar composition have been reported in isolated cases. In such cases discontinue use and contact a physician.

Composition

Barium dental glass
Bis-GMA based hybrid matrix
Pigments
Additives
Catalyst

Shades

Available in 5 shades.
edelweiss T-BLOCK (Translucent Block) in enamel shade.
edelweiss C-BLOCK (Chroma Block) in shades from A0, A1, A2 and A3.
edelweiss i-BLOCK in enamel and chroma shades, A0, A1, A2 and A3.

Block sizes

Available in sizes 12x14x18 mm and 10x12x16 mm

Milling machine compatibility

The T-BLOCK and the C-BLOCK are compatible with the following milling machines:

Manufacturer	Machine
Dentsply Sirona	CEREC Primemill
vhf camfacture AG	All machines with DentalCAM 8 library
DGSHAPE Corporation	DWX-53DC, DWX-52DCi Plus, DWX-52D Plus, DWX-42W Plus
orangedental GmbH & Co. KG	easyMill4, deskMill5, deskMill5 Pro
Amann Girrbach AG	Ceramill Motion 2, Ceramill Motion 3, Ceramill Matik, Ceramill Matron, Ceramill Motion DRS

The i-BLOCK is compatible with the following milling machine:

Manufacturer	Machine
Dentsply Sirona	CEREC Primemill

Application

⚠ **1. Preparation design**

1.1. Minimum thickness at walls should be at least 0.5 mm.
For veneers, minimal cervical thickness of at least 0.3 mm
1.2. Prepare margins with chamfer or rounded shoulder preparation.
1.3. For inlays and onlays, all internal edges and angles should be rounded. Avoid having margins in direct occlusal contact with the opposing tooth.
1.4. Minimum thickness of the restoration should be 1.5 mm in pit and fissure areas and 1.5 mm in cusp areas.

⚠ **2. Milling process**

For information on scanning and CAD/CAM processing, please refer to the respective Instructions for Use and the manuals of the respective CAD/CAM system. The instructions by the manufacturer must be observed. Select the appropriate program for Hybrid Blocks/Composite Blocks and mill in accordance with the instructions for use by the manufacturer.
Following the milling process, check for any defects. If there are any defects like cracks or chipping, the restoration should be discarded.
If the Block size, grinding, or milling parameters are not available, please contact your CAD/CAM system provider in advance.

3. Finishing of milled restoration

For finishing the restoration, appropriate grinding/finishing instruments are needed. Smooth out the attachment point of the Block with fine-grain diamond burs paying particular attention to the proximal contacts. If necessary, carry out individual shape adjustments and smooth out the surface structure created by the CAD/CAM. Final polish is achieved using cotton/linen buffs.

4. Pretreatment of the edelweiss CAD/CAM restoration

4.1. Verify the fit of the restoration on the tooth.
4.2. To improve adhesion, the milled restoration is sandblasted with 25 µm or 50 µm aluminium oxide on the inner fitting surface or roughened with a diamond bur.
4.3. A commercially available resin adhesive bond or enamel bond (e.g. “edelweiss VENEER Bond”, “Parkell Add&Bond Adhesive Composite Primer”, “Bisco All-Bond”, “Clearfil SE Bond”, etc.) can be used to bond the restoration; the instructions for use of the manufacturer of the bond must be observed.

5. Pretreatment of prepared tooth surface

5.1. Isolating and cleaning the preparation: During adhesive luting/cementing protocol thorough isolation of the operating field – preferably with a rubber dam or alternatively with cotton rolls and a saliva ejector.
5.2. Clean the tooth surface using a polishing brush and an oil- and fluoride-free cleaning paste and rinse with water spray. Then lightly dry with water- and oil-free air. Avoid over-drying.
5.3. Apply 37 % phosphoric acid gel to the prepared enamel and then flow the etchant onto the prepared dentin. The instructions for use of the manufacturer of the etchant must be observed.
5.4. Rinse thoroughly with water and gently dry with compressed air.
5.5. Starting with the enamel, thoroughly coat the tooth surfaces to be treated with Dentin Bonding Agent/ Adhesive. The adhesive must be gently scrubbed into the tooth surface for at least 20 seconds and light cured as per manufacturer's instructions.

6. Cementation process

For cementation of edelweiss CAD/CAM BLOCK restorations, pre-treatment of the tooth surface: It is strongly recommended to use an adhesive resin composite cement. For cementation and pre-treatment of the tooth structure follow the instructions for use from the manufacturer of the resin composite cement. To guarantee optimum esthetic results, it is recommended to use an adhesive resin composite cement system that includes a shading system.
6.1. **T-BLOCK (Translucent):** The final shade matching of the restoration can be adjusted using the appropriate composite shades. This can be further individualized by varying the composite shades according to cervical and incisal color variations in the natural tooth. Individual staining of the restoration can be also accomplished using commercially available staining kits; the instructions for use of the manufacturer of the staining kit must be observed.
6.2. **C-BLOCK (Chroma):** These are color matched to correspond to shades A0, A1, A2 and A3 and can be cemented using a resin composite. For substrates that are severely discolored a dentin shade is recommended to provide a more homogenous color.
6.3. Take an appropriate amount of the composite strip in the fingertips and roll into a ball. Using the finger tips, press the ball onto the inside of the restoration. Use the spatula instrument to evenly distribute the composite into the restoration.
6.4. Gently seat the restoration onto the prepared tooth surface and retain it in place exerting uniform pressure.
6.5. Light-cure with a curing light for 2 seconds and remove all excess composite material.
6.6. Final light-cure for 20 seconds on all surfaces and margins with a curing unit with light intensity of 1000 mW/cm².
6.7. Cementation can also be achieved using conventional resin luting cements. When using conventional resin cements, the use of the manufacturer's corresponding bonding agent is recommended.

7. i-BLOCK (implant Block):

The edelweiss implant block features a built-in drill hole that integrates precisely to a titanium base interface or similar attachment.
7.1. Abutment crown as a single unit (Crown + titanium base): The CAD/ CAM fabricated crown can be bonded onto the titanium base extra orally. Screw the crown/titanium base attachment onto the implant.
Seal of the screw channel with composite intraorally.
7.2. For cementing to titanium base follow the instructions of the manufacturer.

8. Finishing and polishing the completed restoration

After having adhesively cemented the restoration, adjust occlusion/articulation with suitable finishing instruments.
Work the interproximal areas with finger-strips then polish with polish-strips.
Polish the cervical areas with silicone-polishing cup.
Final polishing is done with silicone polishers and cotton/linen buffs.

Reusability

The CAD/CAM blocks of edelweiss dentistry production gmbh, are marketed as “single use” (“single use product”). The edelweiss CAD/CAM BLOCKs are intended for single use only. Single-use products must not be reused, as they are not designed to function as intended after the first use.

Waste disposal

Please dispose of the products properly at the end of their service life. The national regulations and disposal guidelines must be observed!

⚠ **Important**

To ensure optimum results, we recommend using the product in combination with all edelweiss components.

⚠ **Mandatory reporting**

All serious incidents related to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Symbols	Description
	Symbol for „Manufacturer“
	Symbol for „Date of manufacture“
MD	Symbol for „Medical device“
REF	Symbol for „Article number“
LOT	Symbol for „Batch code“
	Symbol for „Follow instructions for use“
CE 0482	Symbol for „CE marking of conformity“ with identification number of the notified body
NON STERILE	Symbol for „Non-sterile“
	Symbol for „Do not reuse“
	Symbol for „Attention“
Rx only	Symbol for „Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner“

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CE 0482

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