

Instructions for Use

1. Overview

- Trade / Device Name : Amber Mill Direct
- Common Name : Dental Materials for Dental Prosthesis
- Intended Use of the Device : Amber Mill Direct Series are indicated for fabricating glass ceramic restorations such as single-unit anterior and posterior crowns, veneers, inlays/ onlays and anterior 3-unit bridges using CAD/CAM System.
- Classification Name : Porcelain Powder for Clinical Use
- Packaging Unit : Refer to HASS standard package.

2. Instruction



(1) How to use

This product must be used in accordance with the methods or using a dental CAD/CAM system.

* Procedure for using glass ceramic blocks *

- ① Attach the Jig to the accurate location.
- ② Mount it on the CAD/CAM equipment.
- ③ Input size information of the prepared block into the CAD/CAM equipment.
- ④ Input correction information needed for processing.
- ⑤ Process the Block using the CAD/CAM equipment.
- ⑥ Carefully detach the process-completed block from the equipment.
- ⑦ Detach the processed artificial tooth or restoration from the block.
- ⑧ If necessary, perform stain and glazing treatment.

(2) Storage and Maintenance before Use

- ① Do not store in an open or unhygienic place as this may contaminate the products.
- ② Store away from moisture, direct sunlight, and heat.
- ③ Do not reuse or recycle the remaining part once used.

⚠ 3. Cautions

(1) Cautions before Use

- ① Be careful not to damage the milling tool of the CAD/CAM machine when attaching or detaching the product.
- ② Be careful not to get your hand caught in the milling tool.
- ③ The jig should be attaching to an accurate location.
- ④ Suppress or remove the dust which may occur during the operation of CAD/CAM machine.
- ⑤ Do not drop the product on the ground or apply heavy force as it may damage the product.
- ⑥ Keep the product out of reach of infants and children.
- ⑦ Product should be handled by dental technician.

(2) Storage and Maintenance before Use

- ① Store the product at room temperature in a dry place.
- ② Pack and store the product properly to ensure that it is not damaged.
- ③ Store the product at temperatures ranging from 0°C ~ 40°C, in combination with relative humidity of 10% r.H ~ 90% r.H, under atmospheric pressures ranging from 500 hPa ~ 1060 hPa.

4. Side effect

If the patient is known to be allergic to any of the components of Amber Mill Direct, the material must not be used to fabricate restorations.

5. Contraindication

- ① Posterior bridges reaching into the molar region
- ② 4-and more-unit bridges
- ③ Inlay-retained bridges
- ④ Very deep sub gingival preparations
- ⑤ Bruxism
- ⑥ Cantilever bridges / extension units
- ⑦ Maryland bridges
- ⑧ Any other use not listed in the indications

6. Mechanical and Physical Properties

- ① Material : Glass-ceramics
- ② Flexural Strength : over 300 MPa
- ③ Chemical Solubility : below 100 µg/cm²
- ④ Coefficient of Thermal Expansion : 11.0 (±0.5) x 10⁻⁶ K⁻¹

* This is a single-use product. * Do not reuse.

7. Pictograph

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|--|----------------------------------|--|---|--|---|
| | Do not reuse | | Caution | | Catalogue Number |
| | Consult Instructions for Use | | Batch Code | | Date of Manufacture |
| | Do not use if package is damaged | | Manufacturer | | Authorized Representative in the European Community |
| | Non Sterile | | Rx only | | CE Marking |
| | | | CAUTION: US Federal restricts this device prescription only | | |

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