

Instructions for Use (IFU) – Zirconia Digital Stain Crown

Prescription Use Only

1. Device Description

Zirconia Digital Stain Crown is a patient-specific, single-patient-use dental prosthetic device manufactured for a single patient based on a prescription from a licensed dental professional. The device is supplied non-sterile.

2. Intended Use

Zirconia Digital Stain Crown is a prosthetic device intended to restore the form and function of a natural tooth for long-term use. The device is Rx only, patient-specific, single-unit, single-patient use, and non-sterile.

3. Indications

Restoration of the form and function of a natural tooth, as prescribed by a licensed dental professional using standard clinical techniques.

4. Materials of Construction

The device is fabricated from the following raw materials:

- Zirconia body (primary patient-contacting material) — Dental Zirconia Ceramic (Aidite AiZir), a yttria-stabilized tetragonal zirconia polycrystal (Y-TZP), manufactured by Aidite (Qinhuangdao) Technology Co.
- Surface stain and glaze — Dandy Ceramic Stain and Glaze, manufactured by Zima International, Inc. (DBA Dandy)

5. Contraindications / Limitations

Device use is limited to the scope defined in the Intended Use. (a fixed, single-unit crown restoration of a natural tooth)

Not intended for use when the patient's clinical conditions do not support a prescribed fixed, single-unit crown restoration.

Not intended for patients lacking adequate natural tooth support, preparation, retention, or other clinical conditions necessary to ensure proper placement, retention, and function of a fixed single-unit crown restoration.

Not intended for removable applications.

Not intended for use as a bridge or fixed partial denture, an implant, implant abutment, removable dental appliance, or any restoration type other than a fixed single-unit crown restoration of a natural tooth.

Not intended for use on patients with a known hypersensitivity or allergy to zirconia or to any dental ceramic stain and glaze materials.

6. Prescription Statement

Rx only – For use by or on the order of a licensed healthcare professional.

7. Sterility

The device is supplied non-sterile.

8. Warnings & Precautions

Patient-specific; manufactured for a single patient only. Verify conformity with the prescription prior to use. Do not use if the device is damaged or altered. The use of fixed restorations may have potential risks, including failure, misfit, breakage, debonding, and recurrent caries.

9. Storage & Handling

No shelf life, expiry date, or retest period has been established. Handle with care to prevent damage. Store at room temperature in a clean, dry environment. Protect from contamination prior to use.

10. Device Identifier

The device is supplied under the product codes: ZIRDSSCR

11. Control Number

The lot/control number is unique to each manufactured device and is provided on the package label, identified as "LOT," enabling traceability to the device history record.

12. Cleaning

The device is supplied non-sterile and must be cleaned prior to use. Ensure that the crown is clean and free of any debris.

13. Directions for Use

The device is to be placed by a licensed dental professional using established clinical technique. The following directions apply:

- Ensure that the crown is clean and free of any debris.
- Verify that the device conforms to the prescription and that the fit, margins, and occlusion are correct on the prepared tooth restoration before final seating.
- Cement or bond the restoration following the cement manufacturer's instructions.
- If adjustments are needed, reshape and re-polish as required.
- Remove excess cement and confirm final occlusion.
- Do not use the device if it is damaged or altered.

14. Manufacturer Information

Zima International, Inc. (also DBA Dandy)
1320 N. 300 W. Lehi, Utah 84043
United States

End of Document

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Signatory Table

Action Name	User Name	Title	Signature Date
Approve	Garvin Tran	Manager, Operations - QMS	23-Sep-2026 12:07

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