

Instructions for Use (IFU) – Zirconia Monolithic Crown

Prescription Use Only

1. Device Description

Zirconia Monolithic Crown is a patient-specific, single-use dental prosthetic device manufactured for a single patient based on a prescription from a licensed healthcare professional. The device is supplied non-sterile. The crowns are designed with a minimum wall thickness of 0.6mm and 0.8mm, for anterior and posterior crowns, respectively.

2. Intended Use

A crown is a prosthetic device intended to restore the form and function of a single natural or implant-supported tooth for long-term use. The device is Rx only, patient-specific, single-unit, single-use, and non-sterile.

3. Indications

The device is indicated for the restoration of the form and function of a single natural or implant-supported tooth, as prescribed by a licensed healthcare professional using standard clinical techniques. The device is intended for single-unit restorations only.

4. Contraindications / Limitations

Device use is limited to the scope defined in the Intended Use.

Not intended for use when clinical conditions do not support a prescribed prosthetic restoration.

Not intended for patients lacking adequate tooth support to ensure proper retention and function.

Not intended for removable applications.

Not intended for patients with hypersensitivity or allergy to the device materials

5. Prescription Statement

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

6. Sterility

The device is supplied non-sterile.

7. 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, and recurrent caries.

8. Storage & Handling

The device has no defined shelf life. Handle with care to prevent damage. Store at room temperature in a clean, dry environment. Protect from contamination prior to use.

9. Device Identifier

The device is supplied under the product codes: ZIRMOSCRA2, ZIRMOSCRP2, ZIRMOSCRA1, ZIRMOSCRP1.

10. Control Number

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

11. 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.

12. 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 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.

13. Manufacturer Information

Zima International, Inc. (also DBA Dandy)

1320 N. 300 W. Lehi, Utah 84043
United States

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Signatory Table

Action Name	User Name	Title	Signature Date
Approve	Kasha Lim	Supplier Quality Engineer	11-Sep-2026 13:56

* Datetime fields are displayed according to the system time zone: (GMT-04:00) Eastern Daylight Time (America/New_York)