

Instructions for Use (IFU) – PMMA Crown

Prescription Use Only

1. Device Description

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

2. Intended Use

The PMMA Crown is intended for temporary restoration of the form and function of a natural tooth or implant-supported restoration site for no more than 30 days. The device is Rx only, patient-specific, single-patient use, and non-sterile. The device is not intended for permanent or indefinite use.

3. Indications

Temporary restoration of the form and function of a natural tooth or implant-supported restoration site for no more than 30 days, as prescribed by a licensed healthcare professional using standard clinical techniques.

4. Contraindications / Limitations

Do not use the device beyond 30 days.

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

The device is not intended for long-term, permanent, or indefinite use.

The device is not intended for removable applications.

Do not use when clinical conditions do not support a temporary custom-made prosthetic restoration on a natural tooth or implant-supported restoration site.

Do not use for patients lacking adequate tooth or implant support to ensure proper retention and function.

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. Intended for temporary use only for no more than 30 days. Verify conformity with the prescription prior to use. Do not use it if the device is damaged or altered. The use of temporary dental restorations may have potential risks, including failure, misfit, breakage, debonding, or recurrent caries.

8. Storage & Handling

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: PMMASCRA1 and PMMASCRP1.

10. 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.

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 or implant-supported 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.

13. Manufacturer Information

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

End of Document



This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Approve	Kasha Lim	Supplier Quality Engineer	13-Jul-2026 22:04

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