

Instructions for Use (IFU)

Printed Temp Crown

Custom-Made Medical Device | Prescription Use Only

1. Device Description

Printed Temp Crown is a custom-made 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

A printed temporary crown is a custom-made prosthetic device intended to temporarily restore the form and function of a natural tooth for short-term use (less than 30 days). The device is Rx only, custom-made, and non-sterile.

3. Indications

Temporary restoration of the form and function of a natural tooth for short-term use, as prescribed by a licensed healthcare professional using standard clinical techniques.

4. Contraindications / Limitations

Not intended for long-term use.

Not intended for removable applications.

Use is limited to short-term use as defined in the Intended Use.

Not intended for use when clinical conditions do not support a temporary custom-made prosthetic restoration.

5. Prescription Statement

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

6. Sterility

Non-sterile.

7. Warnings & Precautions

Custom-made for a single patient only.
Intended for temporary use only (less than 30 days).
Verify conformity with the prescription prior to use.
Do not use if the device is damaged or altered.

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. Manufacturer Information

Manufacturer: Zima International, Inc. (also DBA Dandy)
Address: 1320 N 300 W Lehi, Utah 84043
Country of Manufacture: United States

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Signatory Table

Action Name	User Name	Title	Signature Date
Approve	Garvin Tran	Manager, Operations - QMS	09-Sep-2026 14:58

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