

Instructions for Use (IFU)

Crown Emax Layered

Custom-Made Medical Device | Prescription Use Only

1. Device Description

Crown Emax Layered 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 crown is a custom-made prosthetic device intended to restore the form and function of a natural tooth. The device is Rx only, custom-made, and non-sterile.

3. Indications

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

4. Contraindications / Limitations

Not intended for removable applications.

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

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

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.
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: N 300 W, 1320, Lehi, Utah 84043
Country of Manufacture: United States