

# Instructions for Use (IFU)

Bridge – Emax Layered

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## 1. Device Description

The Bridge – Emax Layered is a custom-made dental prosthetic device manufactured based on a prescription from a licensed dental professional. The device is intended for use by qualified dental professionals and is supplied for use in a single patient.

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## 2. Intended Use

A bridge is a custom-made prosthetic device intended to restore the form and function of one or more natural teeth. The device is Rx only, custom-made, and non-sterile.

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## 3. Indications

The device is indicated for patients requiring restoration of tooth form and function as determined by a licensed dental professional.

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## 4. Contraindications / Limitations

- The device is not intended for use outside the oral cavity.
  - The device is not intended for use other than as prescribed by a licensed dental professional.
  - The device is not intended for reuse.
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## 5. Warnings and Precautions

- This device is intended for professional use only.
  - Federal law (Canada) restricts this device to sale by or on the order of a licensed dental professional.
  - The device should be handled in accordance with standard dental laboratory and clinical practices.
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## 6. Prescription Statement

**Caution: Rx only. This device is restricted to use by or on the order of a licensed dental professional.**

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## 7. Sterility

The device is supplied non-sterile.

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## 8. Storage and Handling

**Store the device in a clean, dry environment prior to clinical use. Handle with care to avoid damage or contamination.**

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## 9. Manufacturer Information

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