

## INSTRUCTIONS FOR USE (IFU) - UK CUSTOM-MADE DEVICE (CMD - Custom Made Device)

Device Family: Implant Abutment

GMDN: 63349

Product Code(s): TICLOCDES, TICLOCMED, TICLOCMEG, TICLOCNOB, TICLOCSTR, TICLOCZIM

Manufacturer:

Zima International, Inc. Also DBA Dandy

1320 N. 300 W.

Lehi, UT 84043

United States

Contact:

UK Responsible Person (UKRP):

Name = DANDY LABS GB, LTD

Company Number = 16873608

Registered Address = 5 New Street Square, London EC4A 3TW.

**Intended User:** Prescriber Dental professional / dental practice

**Device Type:** Custom-made dental device (CMD)

**Sterility:** Not supplied sterile (if applicable)

**Single-use / Reusable:** Single-use

### 1) Intended Purpose (Intended Use)

These dental abutments are connected directly to an endosseous implant for use as an aid in prosthetic rehabilitation. The abutment is designed with a scalloped cuff that profiles the natural contours of soft tissue and is custom-made to meet your patient's specific needs. Made from titanium, titanium alloy, or Zirconia..

### 2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dental abutments are designed to be used in the Maxilla or mandible to support a prosthesis on endosseous implants, thereby restoring chewing function for the patient.
- Material: Titanium/Zirconia

[Zirconia](#)

### 3) Contraindications

Do not use in patients:

- Those who are medically unfit for dental implant procedures.
- Those who are allergic or have hypersensitivity to pure titanium or titanium alloy.

- Those where adequate numbers of implants could not be placed to achieve full functional support for a prosthesis.

#### **4) Warnings / Precautions / Potential Risks**

THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING

- For safe and effective use of dental implants, it is strongly suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements, and radiographic evaluations.
- Responsibility for proper patient selection, adequate training, experience in implant placement, and providing appropriate information for informed consent rests with the practitioner. Improper technique can result in implant failure, damage to nerves/vessels, and/or loss of supporting bone.

Cautions:

- New and experienced Implant users should do training before using a new system or attempting a new treatment method.
- Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue. (e.g., poor oral hygiene, uncontrolled diabetes, are on steroid therapy, smokers, infection in the nearby bone, and patients who had oro-facial radiotherapy.)
- Remove the temporary restoration if applicable.
- Verify and re-tighten the screw if applicable. Seal the screw access hole with silicone and cement the final "closed" crown using conventional procedures.
- Make sure that all excess cement is removed from the margin.
- Overtightening of the abutment may lead to screw fracture)
- Cement the final crown or framework using conventional procedures after sealing the access hole, ensuring there's no excess cement on the margin.
- For screw retained restorations
- The final restoration (crown and abutment) is attached to the implant
- Verify the seating
- Tighten the screw to the required torque. (Do not exceed the recommended tightening torque for the abutment screw.

#### **5) Cleaning and Care (Patient Care Instructions — as directed by the dental professional)**

These abutments are not supplied sterile and are intended for single use

#### **6) Storage**

- The product must be stored in a dry, well-ventilated area at room temperature and protected from direct sunlight.
- Incorrect storage may influence device characteristics

#### **7) Expected Life / Service**

A dental abutment typically lasts 10 to 20+ years, often aligning with the crown's lifespan, but can last longer with excellent care; it usually outlasts the crown (10-15 yrs) but is less durable than the implant post. Longevity depends on material, chewing forces (molars wear faster), and habits like grinding (bruxism). Still, good hygiene and regular checkups are key to maximizing its life, with some studies showing great success with all-ceramic options.

## 8) Incident / Complaint Reporting (UK)

Report suspected serious incidents associated with this device to:

- The Manufacturer and/or UK Responsible Person (UKRP) using the contacts above, and
- The UK Medicines and Healthcare products Regulatory Agency (MHRA) in accordance with local requirements.

## 9) Disposal

- Must be disposed of as biological or medical waste if they have been used in a patient's mouth
- Unused abutments (Titanium or Zirconia) may be disposed of as general waste
- Guidelines:
  - Used Abutments:
    - Any dental restoration or component that has been in the patient's mouth is considered biological waste and must be handled and disposed of according to strict medical waste management regulations.
  - Unused Abutments:
    - If the custom abutment is unused and has not been sterilized or come into contact with bodily fluids, it may not fall under the same strict biohazard rules.
- Material:
  - Titanium/Zirconia: The materials themselves (titanium alloy, zirconia) are not inherently hazardous materials in their solid form, but their classification as waste is determined by their potential biohazard contamination during use or the preparation process.
- Recycling:
  - While some materials are recyclable in general construction/demolition waste streams, dental practices must use certified medical waste streams to avoid regulatory non-compliance.
- Follow Local Regulations: Disposal rules are governed by federal, state, and local health and environmental regulations. Ensure your practice is compliant with the specific requirements for your location.