

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

Device Family: Dental Guided Surgery Reference Plate

GMDN: 57949

Product Code(s): SSURGG

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)

Dandy's surgical guide is a disposable medical device customized (3D-printed) for a single patient. The 3D-printed medical device requires steam sterilization before use in surgery.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: It is indicated for intraoral use in guided dental implant surgery, performed by a dental professional.
- Material: Keyguide

[KeyGuide](#)

3) Contraindications

Dental surgical guide contraindications aren't about the guide itself, but the underlying implant procedure; they involve uncontrolled systemic diseases (diabetes, immune issues, clotting disorders, cancer), heavy smoking, insufficient bone, certain medications (bisphosphonates, blood thinners), pregnancy, uncontrolled bruxism, or conditions preventing good oral hygiene, all impacting healing and implant success, with older age (not old) and fully grown jaws being key factors for success

4) Warnings / Precautions / Potential Risks

Potential inaccuracies may arise from poor scans or planning, guide fit issues (such as fractures/poor fit), technology dependence, limited surgical adjustments, and general implant risks, including infection, nerve damage, or sinus perforation. However, guides aim to reduce common surgical errors by improving precision. Key risks stem from the process (planning, imaging) and the procedure itself (implant failure, healing issues).

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

CLEANING

- Thoroughly remove any visible soil remaining on the surface. Alcohol can be used to wipe the
- surface of the surgical guide to ensure a clean part results from this process. No contamination
- shall be found by the naked eye or felt by running fingers on the surface of the part. Special attention
- should be given to edges, hollows, and other geometries.

DRYING

- Dry the part, especially in the hollows and geometries. Compressed air can be used for air drying.

INSPECTION

- Once dried, inspect the medical device for damage or cracks. Replace the part if needed.

DIRECTIONS FOR USE

- To ensure the proper use of the device, dental professionals should follow these steps:
- Wash your hands thoroughly before handling the device.
- Carefully insert the device into the patient's teeth, starting from the back of the patient's mouth and working forward.
- Use your fingers to gently press the device onto the patient's teeth to ensure a snug fit.

6) Storage

The products should be stored in their packaging in a dry place at a normal temperature (18–25°C/64–77°F). Use the sterilized components within the stated time period from the sterile bag.

7) Expected Life / Service

Dental surgical guide itself is a single-use or short-term tool for precise implant placement

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

Dental surgical guide disposal depends on contamination: if blood/saliva-soaked (Regulated Medical Waste), use red biohazard bags/containers for licensed pickup; if clean, it is generally considered regular clinic waste (check local rules). For sharps (drills, wires), use puncture-proof sharps containers. Always follow federal, state, and local regulations and use a licensed medical waste hauler for hazardous/infectious waste.