

Instructions for Use (IFU)

Product: Custom-Made Dental Device
Manufacturer: Alto Dental BV
Intended Users: Licensed dental professionals and surgeons
Compliance: MDR 2017/745

1. Intended Use

Custom-made Medical Device	Intended Use
Temporary Full-Arch Bridges	Intended for the temporary replacement of teeth.
Permanent Full-Arch Bridges	Intended for the replacement of teeth permanently
Temporary Crowns	Intended for the temporary replacement of single tooth crowns or multiple teeth crowns.
Permanent Crowns	Long-term restoration of a single tooth or multiple teeth, designed to restore strength, shape, and size.
Dental teeth shells	Intended for the replacement of teeth shell on titanium arch bars.
Night guard for teeth	Intended for protecting the teeth of an individual during sleep.
Orientation plates for dental surgery	Intended for the orientation and placement of the multi-units during surgery.

2. Contraindications

These devices should **not** be used in the following circumstances:

- **Allergies:** Known hypersensitivity or allergy to the specific materials used (e.g., specific resins, PMMA, Zirconia, or metal alloys).
- **Insufficient Support:** Inadequate bone density or lack of healthy tooth structure to support the bridge or crown.
- **Active Infection:** Presence of untreated periodontal disease or acute periapical infection in the area of placement.
- **Poor Compliance:** Patients with severe mental or physical disabilities that prevent proper oral hygiene or maintenance.

3. Expected Undesirable Side Effects

While these devices are custom-fitted, some patients may experience:

- **Minor Discomfort:** Initial "tightness" or pressure after fitting.
- **Sensitivity:** Temporary sensitivity to hot or cold temperatures, especially with crowns and bridges.
- **Speech Alteration:** A short period of adaptation (usually 1–2 weeks) may be required for clear speech.
- **Gingival Irritation:** Minor inflammation of the gums surrounding the device.
- **Taste Changes:** Some patients report a temporary change in taste perception immediately following cementation.

4. Warnings and Precautions

- **Professional Use Only:** These devices must only be fitted, adjusted, or removed by a qualified dental professional.
- **Single Patient Use:** As custom-made devices, they are intended for the named patient only. **Do not attempt to use on another person.**
- **Fragility:** Temporary devices are made from materials with lower fracture resistance. Avoid excessively hard or sticky foods.
- **Choking Hazard:** If a device becomes loose or breaks, remove it immediately (if possible) and contact your dentist to prevent accidental swallowing or inhalation.
- **Surgical Accuracy:** Orientation plates must be inspected for fit before surgery. If the plate does not seat perfectly, do not use it for implant positioning.

5. Patient Information: Maintenance and Cleaning

For Fixed Devices (Permanent/Temporary Crowns and Bridges)

- **Brushing:** Brush at least twice daily using a soft-bristled toothbrush and non-abrasive fluoride toothpaste.
- **Flossing:** Use specialized "bridge threaders" or interdental brushes to clean the gaps underneath bridges and around crowns where a standard brush cannot reach.
- **Avoid Trauma:** Do not use your teeth as tools (e.g., opening bottles or biting fingernails), as this can chip the porcelain or resin.

For Removable Devices (Night Guards and Orientation Plates)

- **Daily Cleaning:** Rinse with lukewarm water immediately after removal. Clean thoroughly with a soft toothbrush and mild, fragrance-free soap.
- **Storage:** When not in use, store the device in the provided ventilated protective case. Keep it away from high heat (direct sunlight, boiling water), which can warp the custom shape.
- **Soaking:** You may use dedicated dental appliance cleaning tablets 1–2 times a week, following the manufacturer's timing instructions.

6. Storage & Disposal

- Do not use if the packaging and/or product is damaged
- Do not use if the product doesn't meet the specification from the prescription
- Dispose of as medical waste per local regulations

7. Contact



Alto Dental BV

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8. Symbols used



Manufacturer

Medical Device

Lot number – Unique identifier

Non-Sterile product

Please observe instructions for use

Manufacturing date

(*) Symbols are part of the label provided with Custom-made medical devices by manufacturer Alto Dental BV.