

Instruction for use - Analog

Product name: Analog

Models/specifications:

| No. | Name | Models/ specifications | No. | Name | Models/ specifications |
|-----|----------------|---------------------------|-----|--------------------------|---------------------------|
| 1 | Common analog | TD-BSM | 3 | Common composite analog | TD-FH-BSM |
| 2 | Digital analog | OTD-BSM | 4 | Digital composite analog | OTD-FH-BSM |

Product description: The product consists of an analog and a nut. It is made of TC4 titanium alloy. The product is not manufactured using additive manufacturing processes and is supplied in non-sterile.

Intended use: It is used as an auxiliary consumable in the process of implant implantation or crown making.

Intended user: A trained professional operator or physician.

Intended population: It is intended for patients requiring dental implants.

Product performance: The main performance requirements are as follows.

| | |
|------------|---|
| Appearance | The surface should be free of defects such as scratches, cracks, sharp edges, burrs, edge curls, and dirt. |
| Dimensions | The length tolerance of the product should be ± 0.2 mm and the diameter tolerance should be ± 0.1 mm. |
| Surface | The roughness Ra of the outer surface should be $\leq 1.6 \mu\text{m}$. |

Contraindications: None.

Precautions:

The device is supplied in non-sterile, does not need to be sterilized or disinfected prior to use and may not be used directly on patients.

Warnings and suggestive notes:

- ① Products cannot be recycled;
- ② Damaged and incomplete products cannot be used;
- ③ Select an analog that matches the specifications of the implant implanted in the

patient. If the analog of non-matching specifications is used, the final upper prosthesis will fail.

- ④ The analog is used only for its intended use and any modification of the product is strictly prohibited.
- ⑤ The common analog and common composite analog are used alone, and the digital analog and digital composite analog are used with nuts.
- ⑥ When users discover any serious incidents related to the device, they should report them to the manufacturer, or the competitive authorities.
- ⑦ Disposal of waste by the user in accordance with the requirements of the regulations.

Usage:

(1) How to use plaster mold

1. Unwrap and take out the analog, connect and match the analog and the transfer post;
2. Insert the transfer post into the impression;
3. Pour plaster and embed the analog in the plaster mold;
4. After the plaster mold is cured, remove the transfer post;
5. Connect the abutment or accessory to the analog for subsequent operation.

(2) How to use 3D printing resin model

1. Before printing the resin model, import the analog data of the corresponding model into the resin model design data, so that the resin model leaves space for the analog when printing;
2. Unwrap and take out the digital analog, put it into the analog space corresponding to the printed resin model, and tightly lock the analog on the resin model with a nut at the bottom of the analog;
3. Connect the abutment or accessory to the analog for subsequent operation.

Packaging instructions: The product is packed in an aluminum foil bag or a blister packing box.

Storage condition: This product should be stored in a room free of corrosive gases and protected from direct sunlight.











Transportation condition: During transportation, it is necessary to prevent severe

extrusion and vibration, protect against snow and rain, and it is not allowed to be mixed with corrosive substances.

Date of manufacture: See product label

Shelf-life:N/A.

Description of label symbols:

| | | | | | |
|---|---|---|---------------|--|---|
|  | Date of manufacture |  | Batch code |  | Consult instructions for use or consult electronic instructions for use |
|  | Caution |  | Do not re-use |  | Manufacturer |
|  | Medical device |  | CE mark |  | Authorized representative in the European Community/ European Union |
| Rx only | US Federal Law restricts this device to sale by or on the order of a physician or dentist |  | Serial number | | |

Manufacturer's name: Chengdu Besmile Medical Technology Co., Ltd.

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