

Instruction for use - Scan body

Product name: Scan body

Models/specifications: See label.

Product description: The product consists of the scan body and the screw, in which the scan body is made of Ti-6Al-4V titanium alloy; the screw is made of Ti-6Al-4V ELI titanium alloy. The product is used during dental implant procedures. The product is supplied in non-sterile. It should be sterilized by users according to the IFU prior to use.

Indication: Implant prosthetic rehabilitation.

Intended use: For dental implant procedures.

Intended user: A trained professional operator or physician.

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

Product performance:

Appearance	The surface of the product should be free of defects such as dirt, scratches, cracks, sharp edges, burrs, edge curls, tool marks and gaps.
Coating	The coated part of the coated scan body should have uniform color and no dull metallic color.

Contraindications: None.

Precautions:

- ① Please carefully check the packaging and products inside before use, and do not use if damaged;
- ② Avoid collision with hard objects, and avoid severe extrusion, stress and vibration during handling;
- ③ Handle the product carefully to avoid damage to the product due to falling. Do not use the product after falling;
- ④ The product needs to be adjusted and used by a professional technician or professional doctor.

Warnings and suggestive notes:

- ① Damaged and incomplete products cannot be used;

- ② Improper use or mismatched model may shorten the service life of the product.
- ③ The product should be sterilized before use in the mouth. It is recommended to sterilize the product by pressure steam. Recommended sterilization parameters: 121 °C, duration: 20 min.
- ④ When users discover any serious incidents related to the device, they should report them to the manufacturer, or the competitive authorities.
- ⑤ Disposal of waste by the user in accordance with the requirements of the regulations.

Usage:

- ① Connect the scan body with an implant implanted in the alveolar bone or an analog in the dental mold before implant restoration;
- ② Scan the scan body by a scanner;
- ③ Overlap the raw data of the scan body in the design software with the scanned data to determine the implant or analog position;
- ④ Implant repair design is performed on a well-positioned implant.

Packaging instructions: The product is packed in the aluminum foil bag or 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.

Use condition: The product should be used by trained professional operators in legal and formal custom-made denture manufacturing institutions, or used by trained doctors in regular dental clinics and hospitals.

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
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	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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