Instruction for use - Impression Post

Product name: Impression Post

Models/specifications:

No.	Name	Models/ specifications	No.	Name	Models/ specifications
1	Closed tray Impression Post	ZYC-BSM	5	Closed tray Impression Post screw	ZYLD-C-BSM
2	Open tray Impression Post	ZYO-BSM	6	Open tray Impression Post screw	ZYLD-O-BSM
3	Composite closed tray Impression Post	ZYC-FH-BSM	7	Composite closed tray Impression Post screw	ZYLD-CFH-BSM
4	Composite open tray Impression Post	ZYO-FH-BSM	8	Composite open tray Impression Post screw	ZYLD-OFH-BSM

Product description: The product consists of the impression post and the screw, in which the impression post is made of Ti-6Al-4V titanium alloy; the screw is made of Ti-6Al-4V ELI titanium alloy. The product is not manufactured using additive manufacturing processes and is supplied in non-sterile. It should be sterilized by users according to the IFU prior to use.

Indication: Restoration of the esthetics and functionality of the teeth in partially or fully edentulous patients.

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 doctor.

Intended environment: This product is expected to be used in denture manufacturing institutions dental clinics, hospitals.

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

Product performance:

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 roughness	The roughness Ra of the outer surface should be ≤ 1.6 μm.

Contraindications: None.

Precautions:

1. Fully understand the contents of the IFU before use;

2. The product needs to be used with corresponding implants, analogs or composite abutments. Fully understand the supporting information before use;

3. When operating in the oral cavity, take precautions to prevent inhalation or accidental swallowing.

Warnings and suggestive notes:

① Select a Impression Post that matches the specifications of the implant or composite abutment implanted in the patient. If the Impression Post of non-matching specifications is used, the final upper prosthesis will fail.

② The Impression Post is used only for its intended use and any modification of the product is strictly prohibited.

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. Unwrap and take out the Impression Post; Sterilization according to recommended sterilization parameters;

2. Connect the Impression Post and the implanted implant or composite abutment, and lock it tightly with screws;

3. Take the impression

3.1 For the closed tray Impression Post, after injecting silicone rubber, directly use the impression material to take the impression, remove the Impression Post after taking the impression, fix it in the analog, and then insert it into the taken impression;

3.2 For the open tray Impression Post, cut off the impression material at the ejection position of the screw when taking the impression, inject silicone rubber, remove the screw after pressing the mold, and connect the analog;

4. Pour plaster to duplicate the model.

Package: 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.

Shipping 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.

Manufacturer's address: No.9, Sec.2, Shengwucheng North Rd., Chengdu Tianfu International Bio-Town, Shuangliu District, Chengdu, Sichuan 610200, P.R.China.

Contact information: 028- 68907833

European representative name: MedPath GmbH

ADD: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

TEL: +49(0)89 189174474

E-mail: info@medpath.pro