

Customized Abutment and Screw Instructions for Use



Model: Customized Abutment and Screw

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Instructions for Use

Instructions (Customized Abutment and Screw)

Product name: Customized Abutment and Screw

Model: See label.

Composition: The Customized Abutment and Screw is composed of two parts: the customized abutment and screw. Among them, the customized abutment is machined from Ti-6Al-4V titanium alloy material in accordance with ASTM F1472, and the screw is machined from Ti-6Al-4V ELI titanium alloy material in accordance with ASTM F136.

Indication: Customized Abutment and Screw is used as a complement component for dental implants placed in the jawbone after tooth loss, to connect, support and retain the restoration or implant superstructure. Customized Abutment and Screw is indicated for single unit restorations.

Customized Abutment and Screw is compatible with the following Implant Systems:

No.	Implant System Compatibility	Implant Body Diameter(mm)	Platform Diameter(mm)
1	Straumann Bone Level RC 4.1, RC 4.8 (composed of pure titanium)	4.1,4.8	4.1,4.8
2	Straumann Bone Level NC 3.3 (composed of pure titanium)	3.3	3.3
3	Nobel Biocare Active NP3.5	3.5	3.5
4	Nobel Biocare Active RP4.3/5.0	4.3,5.0	3.9,3.9

All digitally designed abutments for use with Customized Abutment and Screw are intended to be manufactured at a BESMILE validated milling center

Intended patient population: It is suitable for clinical patients with dentition defect or missing.

Intended users: The target users of this product are hospitals, clinics or dental technicians. Users need to acquire relevant skills, knowledge and professional training before using this product.

Contraindication: Contraindicated for those allergic to raw materials.



Prohibited beyond the scope of personalized processing.

Product performance:

Surface defect	No discontinuous defects on the surface.
Attachments	No visible attachments should be found.

Precautions:

- (1) The user must read these instructions carefully and use the product as directed;
- (2) The instructions provided must be used under the guidance of an experienced implantologist with credentials and training;
- (3) It is the user's responsibility to decide whether the product is suitable for the patient, and we do not assume any responsibility for any kind of misdiagnosis or operational errors made by the user;
- (4) When performing implant restorations, measures must be taken to prevent the product from being inhaled or swallowed in the mouth;
- (5) Users must also learn the latest achievements of implant restorations and their application specifications, and once in doubt, please contact our company immediately to solve the problem;
- (6) Overloading and weight-bearing exercise is strictly prohibited, please follow the doctor's advice;
- (7) Before use, confirm the specifications and models of Customized Abutment and Screw.

Warnings:

- (1) The product cannot be recycled;
- (2) Damaged and incomplete products cannot be used;
- (3) Improper selection of specifications and models may make the finished product unusable;
- (4) The product is for single-use only.
- (5) Reuse of the product can result in loss of functionality and/ or infections.
- (6) Since the Customized Abutment and Screw are small, they must be handled with caution to avoid the risk of swallowing or aspiration by the patient.



- (7) Place implant-borne restorations in occlusion only when the implant is completely osseointegrated.
- (8) Always place temporary restorations out of occlusion.
- (9) Allergies to the titanium alloy may very rarely occur.
- (10) The Customized Abutment and Screw must be used and handled only by dental professionals.
- (11) Small diameter implants and angled abutment are not recommended for the posterior region.
- (12) This product is compatible only with the pure titanium Straumann device.

MRI Safety Information

This product is made of metal materials and can withstand the influence of magnetic resonance energy. Full MRI safety information is available in the MRI Safety Information section of the Prosthetics Manual, which can be obtained at BESMILE sales or by calling 028- 81501188.

Sterilization instruction

The Customized Abutment and Screw is supplied in non-sterile and must be sterilized before being placed in the patient's mouth. The product is clean when it is dispatched from the factory and does not need to be cleaned and disinfected before sterilization.

Besmile recommends the following methods for sterilization:

Sterilization method	Sterilization parameters	Drying time
Gravity-Displacement Steam Sterilization	Sterilization temperature: 121°C (250°F), sterilization time: 30min;	80°C (176°F) Dry for 15 min

For sterilization, the device should be wrapped in a wrap that is FDA-cleared for the indicated cycles.

Instructions for use:

- (1) Before use, confirm that the specifications and models of the Customized Abutment and Screw match;
- (2) Sterilize the product;



- (3) Install the Customized Abutment and Screw and confirm the installation;
- (4) Check the occlusion;
- (5) Install the upper restoration.

Package: Packed in medical aluminum foil film bag or blister box.

Storage condition: This product should be stored in a well-ventilated, clean, and non-corrosive gas room.

Shipping Condition: In the process of transportation, it is necessary to prevent violent extrusion and vibration, prevent snow and rain from soaking, and do not mix with corrosive substances.

Date of manufacture: See 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		Non-sterile	Rx only	US Federal Law restricts this device to sale by or on the order of a physician or dentist

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- 81501188

Issue date: 2025.08.29

Version: A00

Instructions (Pre-milled Blank)

Product name: Pre-milled Blank

Model: See label.

Composition:

Pre-milled Blank is composed of two parts: titanium column and screw. The titanium column is machined from Ti-6Al-4V titanium alloy material in accordance with ASTM F1472; The screw is machined from Ti-6Al-4V ELI titanium alloy in accordance with ASTM F136.

Indication: Customized Abutment and Screw is used as a complement component for dental implants placed in the jawbone after tooth loss, to connect, support and retain the restoration or implant superstructure. Customized Abutment and Screw is indicated for single unit restorations.

Customized Abutment and Screw is compatible with the following Implant Systems:

No.	Implant System Compatibility	Implant Body Diameter(mm)	Platform Diameter(mm)
1	Straumann Bone Level RC 4.1, RC 4.8 (composed of pure titanium)	4.1,4.8	4.1,4.8
2	Straumann Bone Level NC 3.3 (composed of pure titanium)	3.3	3.3
3	Nobel Biocare Active NP3.5	3.5	3.5
4	Nobel Biocare Active RP4.3/5.0	4.3,5.0	3.9,3.9

All digitally designed abutments for use with Customized Abutment and Screw are intended to be manufactured at a BESMILE validated milling center.

Intended patient population: It is suitable for clinical patients with dentition defect or missing.

Intended users: The target users of this product are hospitals, clinics or dental technicians. Users need to acquire relevant skills, knowledge and professional training before using this product.

Contraindication: Contraindicated for those allergic to raw materials.

Product performance:

Surface defect	No discontinuous defects on the surface.
Attachments	No visible attachments should be found.

Caution:

(1) Users should read the instruction carefully, and use the product according to the requirements.



- (2) The product needs to be made by the professional technicians.
- (3) The product needs to be prevented from splashing during use. Goggles are recommended to use during processing.

Warning:

- (1) The product cannot be recycled;
- (2) Damaged and incomplete products cannot be used;
- (3) Improper selection of specifications and models may make the finished product unusable;
- (4) The interface of the Pre-milled Blank, which being connected to the implant, must never be changed or modified. Modifications of the interface may result in loss of functionality and/ or infections.
- (5) The product is for single-use only.
- (6) Reuse of the product can result in loss of functionality and/ or infections.
- (7) Since the Customized Abutment and Screw are small, they must be handled with caution to avoid the risk of swallowing or aspiration by the patient.
- (8) Place implant-borne restorations in occlusion only when the implant is completely osseointegrated.
- (9) Always place temporary restorations out of occlusion.
- (10) Allergies to the titanium alloy may very rarely occur.
- (11) The Pre-milled Blank components must be used and handled only by dental professionals.
- (12) The use of torque value higher than the recommended may result in damage to the Pre-milled Blank, and/or the implant. The use of torque values lower than those recommended may result in loosening of the Pre-milled Blank, which may result in damage to the Pre-milled Blank and/or the implant.
- (13) Small diameter implants and angled abutment are not recommended for the posterior region.
- (14) This product is compatible only with the pure titanium Straumann device.

MRI Safety Information

This product is made of metal materials and can withstand the influence of magnetic resonance energy. Full MRI safety information is available in the MRI Safety Information section of the Prosthetics Manual, which can be obtained at BESMILE sales or by calling 028-81501188.

Sterilization instruction

Pre-milled Blank is supplied non-sterile and must be sterilized before being placed in the patient's mouth after being fabricated into abutments.

Besmile recommends the following methods for sterilization:

Sterilization method	Sterilization parameters	Drying time
Gravity-Displacement Steam Sterilization	Sterilization temperature: 121°C (250°F), sterilization time: 30min;	80°C (176°F) Dry for 15 min

For sterilization, the device should be wrapped in a wrap that is FDA-cleared for the indicated cycles.

Instructions for use:

- (1) Confirm the product's specifications and models before use;
- (2) Confirm whether the processing equipment used in CAD/CAM meets the machining requirements;
- (3) Composing and cutting;
- (4) Take down the customized abutment processed at the upper part;
- (5) Grinding and polishing;
- (6) Washing.

Package: Pre-milled Blank is packed in medical aluminum foil film bag.

Storage condition: This product should be stored in a well-ventilated, clean, and non-corrosive gas room.

Shipping Condition: In the process of transportation, it is necessary to prevent violent extrusion and vibration, prevent snow and rain from soaking, and do not mix with corrosive substances.

Date of manufacture: See 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		Non-sterile	Rx only	US Federal Law restricts this device to sale by or on the order of a physician or dentist
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