Prosthetics Manual

1. Indications for Use

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

2. Device Description

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. And the surface of product is not modified. The lower part of the product has a fixed interface shape, and the upper part is machined according to the needs of the patient. In the process of dental implant surgery, as the upper structure of the implant, it is installed on the implant platform anchored in the bone, which plays the role of supporting, retaining and stabilizing the prosthesis.

Customized Abutment and Screw is created via use of the Pre-milled Blank.

The information of the Implant Systems compatible with the product is detailed in

Table 1.

Table 1 Compatible Implant Systems

No.	Model	Implant System Compatibility	Implant Body Diameter (mm)	Platform Diameter (mm)	510(k)	Implant Name	Company Name
1	QU-02	Straumann Bone Level RC 4.1, RC 4.8 (composed of pure titanium)	4.1,4.8	4.1,4.8	K140878	Straumann® Bone Level Tapered Implants	Straumann USA, LLC
2	QU-03	Straumann Bone Level NC 3.3 (composed of pure titanium)	3.3	3.3	K140878	Straumann® Bone Level Tapered Implants	Straumann USA, LLC
3	HE-04	Nobel Biocare Active NP3.5	3.5	3.5	K142260 K083205	NobelActive ® NobelActive 8.5 mm & 18.0 mm	Nobel Biocare AB
4	HE-05	Nobel Biocare Active RP4.3/5.0	4.3,5.0	3.9,3.9	K142260 K083205	NobelActive ® NobelActive 8.5 mm & 18.0 mm	Nobel Biocare AB

3.Contraindications

Contraindicated for those allergic to raw materials.

4.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 interface of the product, 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.

5.Precautions

In order to ensure the best possible conditions for successful working of an implant, it is strongly recommended that the laboratory that designs the superstructure and the surgeon and dentist who install the components all work closely together throughout the processing of the implant.

Only dental surgeons who have undergone approved training in dental implantology should fit the final abutment. Only laboratory employees with the relevant training should design the final abutment.

6.Potential adverse events

Potential adverse events associated with the use of the Pre-milled Blank products may include: failure to integrate, loss of integration and infection.

7.MRI Safety Information

MR Conditional

Warning: The RF safety of the device has not been tested. The patient may only be

imaged by landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the RF coil.

A patient with this device can be scanned safely in an MR system under the following conditions:

 **MR Conditional** A person with this device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.	
Device Name	Customized Abutment and Screw
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

8.Sterilization

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℃(250℉) Sterilization time: 30min	80℃ (176℉) Dry for 15 min

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

9. Surgical planning and implant insertion

Besmile is not providing implants. For surgical planning and implant insertion, follow the instruction for use and surgical guide issued by the original implant manufacture.

10. Prosthetic procedure (Validated milling facility)

10.1 Using digital workflow (intra-oral scanning)

(1) For detection of the precise implant position during scanning, use the Scan Body. This must be selected to be compatible with the relevant implant/abutment platform.

(2) Scan the patients teeth setup by use of a dental Intra-oral scanner

Optional:

(3) Create a digital working model in the design software.

(4) Export the STL file from the design software and send the STL file to your 3D printer or external 3D print provider.

(5) Place an Analog for printed models in the 3D printed working model. This must be selected to be compatible with the relevant implant/abutment platform.

10.2 Using semi-digital workflow (desktop scanning)

(1) Obtain conventional impression of patient teeth setup and create working model with placed enclosed analog to representing the implant.

(2) Place a Scan Body in the analog to identify the position and orientation of this representing the implant.

(3) Scan the working model by use of a dental desktop scanner.

10.3 Designing and creating the Customized Abutment

The Pre-milled Blank must be designed using appropriate design software with appropriate library files installed. The wall thickness should not be less than 0.5 mm. The transgingival height should not be less than 1mm or exceed 5 mm. The maximum angulation should not exceed 30°. The post height should not be less than 4 mm or exceed 12 mm.

(1) Import the digitized patient information from the intraoral scan to the design software.

(2) Import library file and select relevant implant platform from the library.

(3) Design the Pre-milled Blank in the design software.

(4) The digital file of the Pre-milled Blank must be sent to a Besmile validated milling facility for manufacturing.

(5) Visually inspect the implant-abutment connection of the customized abutment for any damage which may have been caused during the milling machine processing.

11. Finalizing the prosthetic restoration

(1) Place the Pre-milled Blank in the working model with the model analog and a process screw.

(2) Complete the crown/bridge restoration following routine laboratory procedures.

12. Use and handling for the dentist

The dentist receives the final dental restoration / working model with the Prosthetic screw from the dental lab.

(1) Identify and unpack the Prosthetic screw(s).

(2) Clean, disinfect and sterilize dental restoration and Prosthetic screw(s).

(3) Remove the healing cap, closure screw or temporary restoration from patient's mouth.

(4) Gently, insert the dental restoration into the patient's mouth in proper position to the implant(s) or abutment(s).

(5) Place corresponding Prosthetic screw(s) in the dental restoration and tighten screw(s) to the recommended torque (refer to the table below).

Implant Platform compatibility	Recommended Screw torque
Nobel Biocare Active NP3.5	20Ncm
Nobel Biocare Active RP4.3/5.0	20Ncm
Straumann BL NC	35Ncm
Straumann BL RC	35Ncm

(6) In order to obtain the recommended torque a dental torque wrench with a suitable screwdriver must be used in accordance with the relevant manufacturer‘s instructions.

(7) The screw channel must always be sealed after the abutment is attached to the

implant.

13. List of FDA registered Besmile validated milling facility

VMC 1 Name:

Address:

Telephone number:

Email:

14. Caution

U.S. Federal Law restricts this device to sale by or on order of a dentist or physician.

15. Further information

For additional information about the use of Besmile products, please contact your local sales representative.

16. Storage condition

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

17. 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.

18.Disposal

The dental restoration must be disposed as biological waste.

19. 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