

User Manual for Machinable Abutment Blank and Central Screw

[Product Name]

Machinable abutment blank and central screw

[Structure and Composition]

Composed of a machinable abutment blank and a central screw, both made of TC4ELI material, designed and machined by CAD/CAM. The interface is fixed and connected to the implant, and the upper shape is machinable. The surface has not been treated. Provided in a non sterile state, it can be milled into customized abutments.

[Scope of Application]

After machining the machinable abutment blank into a customized abutment, it can be used as a matching component for dental implants implanted in the jawbone after tooth loss, for connecting, supporting, and fixing the upper structure of the restoration or implant. The central screw is used to connect and fix the implant and customized abutment.

[Specifications and Types]

Table 1: Specification and Type Table

Connection method with the implant	Type	Tightening Torque (Ncm)	Matching screw type
Inner triangle	MB01-01	25	AS01-01
	MB01-02	20	AS01-02
	MB01-03	20	AS01-02
	MB01-01	20	AS01-03
Cross lock	MB02-01	35	AS02-01
	MB02-02	35	AS02-02
Inner hexagon	MB03-01	35	AS03-01
	MB03-02	30	AS03-02
	MB03-03	20	AS03-03
	MB03-04	30	AS03-01
	MB03-05	35	AS03-05
	MB03-06	35	AS03-06
Inner octagon	MB04-01	35	AS04-01

[Product Performance]

The machinable abutment blank and central screw meet the performance requirements of TC4ELI titanium blank in GB/T13810.

[Contraindication]

- Patients with severe uncontrolled systemic diseases, bone metabolism disorders, and uncontrollable bleeding disorders;
- Pregnant women, children, uncooperative patients, and those who are deemed unsuitable for implantation surgery by doctors;
- Patients with drug abuse, alcoholism, smoking, mental illness, and long-term treatment of sexual dysfunction;
- Patients with dry mouth, weakened immune system, and white blood cell disorders;
- Patients with diseases that require regular use of steroids, titanium allergies, and uncontrollable endocrine disorders;
- Local contraindications: Insufficient bone mass, poor bone quality, and residual tooth roots in the local area.
- Related contraindications: bone irradiation treatment, diabetes, drug anticoagulation/bleeding quality, bruxism, abnormal functional habits, complex anatomical bone morphology, tobacco abuse, uncontrolled periodontitis, temporomandibular joint diseases, pathological jaw diseases, oral mucosa abnormalities that need treatment, pregnant women, poor oral hygiene.

[Warnings and Precautions]

1. This product should be processed in the upper form by a manufacturer who is skilled in technology and has certain processing capabilities, and the processing range should comply with the provisions of Table 2.
2. This product is a disposable item and cannot be reused.
3. The abutment milled from this product should be used in combination with porcelain crowns, all ceramic crowns and other dental crowns during repair, and the bonding and fixation should be firm
4. Medical device waste shall be disposed of in accordance with the 《Regulations on the Management of Medical Waste》 .

[Instructions for Use]

The machinable abutment blank is used for upper restoration of dental implants. It is designed and machined through CAD/CAM and other methods. The machining range is shown in Table 2. It is mainly used for customized aesthetic restoration, bonding fixation, and tightening abutment torque as shown in Table 1.

[Sterilization and Packaging]

This product is non-sterile packaging

[Product Maintenance and Maintenance Method]

None

[Storage Conditions]

Storage at room temperature

[Production Date]

See the label

[Period of Validity]

Not applicable

[Production License No.]

Producing Certificate No.20245496 of Guangdong Drug Instrument Administration

[Medical Device Registration Certificate No.]

National Medical Device Approval No. 20243171229

[Product Technical Requirements No.]

National Medical Device Approval No. 20243171229

[Revision Date of Manual]

None

[Registrar / Manufacturer / After-Sales Service Unit]

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[Contact Information]

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Table 2 Processing range of milling table blank

Connected method	Type of machinable abutment blank	Adaptive implant information			Machine range
		Adapt to the implant series	Manufacturer	Registration certificate number	
Inner Triangle	MB01-01	Diameter: Ø 3.4, Ø 4.0, Ø 4.6, Ø 5.2 (mm) Length: 6.5-18 (mm)	Antogyr Co. Ltd	National Medical Device Registration (Import) No. 20153171463	AH: 4.0~6.0mm Abutment diameter: 4.0~5.0mm GH: 0.75~3.75mm Angle: 0~23°
	MB01-02	Diameter:Ø3.8(mm) Length: 11-16 (mm)	ALTATEC GmbH Co., Ltd	National Medical Device Registration (Import) No. 20153170036	AH: 4.0 ~8.4mm Abutment diameter: 5.3mm GH: 1.0~3.0mm 1.8~4.5mm Angle: 0~20°
	MB01-03	Diameter:Ø4.3(mm) Length: 9-16 (mm)			AH: 4.0 ~8.4mm Abutment diameter: 5.8mm GH: 1.0~3.0mm 1.8~4.5mm Angle: 0~20°
	MB01-04	Diameter:Ø5.0(mm) Length: 9-16 (mm)			AH: 4.0 ~8.6mm Abutment diameter: 6.5mm GH: 1.0~3.0mm 1.8~4.5mm Angle: 0~20°

Cross lock	MB02-01	Diameter: Ø3.3(mm) Length: 8-14 (mm)	Straumann Research Co., Ltd	National Medical Device Registration (Import) No. 20153170691	AH: 4.0~5.4mm Abutment diameter: 4.3mm GH: 2.0~3.5mm Angle: 0~ 15°
	MB02-02	Diameter: Ø 4. 1,4.8 (mm) Length: 8-14 (mm)			AH: 4.0~7.4mm Abutment diameter: 6.5mm GH: 2.0~3.5mm Angle: 0~ 15°
Inner hexagon	MB03-01	Diameter: Ø 3.9, Ø 4.3, Ø 4.8, Ø 5.3, Ø 6.3, Ø 7.3 (mm) Length: 7-14.5 (mm)	Korea MegaGen Implant Co., Ltd	National Medical Device Registration (Import) No. 20193170358	AH: 4.0mm Abutment diameter: 4.5~6.5mm GH: 1.0~6. 1mm angle:/
	MB03-02	Diameter: Ø 3.6, Ø 4.0, Ø 4.5, Ø 5.0, and Ø 5.8 Length: 7-16 (mm)	Dentium Co., Ltd	National Medical Device Registration (Import) No. 20163172232	AH: 4.0-8.8 mm Abutment diameter: 4.5~5.5mm GH: 1.0~4.0mm Angle: 0~25°
	MB03-03	Diameter: Ø3.5(mm) Length: 8.5-15 (mm)	Osstem Implant Co., Ltd	National Medical Device Registration (Import) No. 20153172257	AH: 4.0 ~8.0mm Abutment diameter: 4.5mm GH: 2.0~4.0mm Angle: 0~ 17°
	MB03-04	Diameter: Ø 4.0, Ø 4.5, Ø 5.0, Ø 6.0, and Ø 7.0 Length: 7-15 (mm)			AH: 4.0 ~8.0mm Abutment diameter: 5.0~6.0mm GH: 2.0~4.0mm Angle: 0~ 17°

	MB03-05	Diameter:Ø3.75(mm) Length: 7-18 (mm)	NobelBiocare Biotechnology Co., Ltd	National Medical Device Registration (Import) No. 20153173818	AH: 4.0~6.5mm Abutment diameter: 4.8mm GH: 1.5~3.0mm Angle: 0~ 15°
	MB03-06	Diameter:Ø4.3, Ø5.0(mm) Length: 7-18 (mm)			AH: 4.0~6.5mm Abutment diameter: 5.0mm GH: 1.5~3.0mm Angle: 0~ 15°
Inner octagon	MB04-01	Diameter:Ø4.8(mm) Length: 6-14 (mm)	Straumann Research Co., Ltd	National Medical Device Registration (Import) No. 20153170691	AH: 4.0 Abutment diameter: 5.05-6.0 GH: / angle:/