Use Manual for Customized Abutment and Accessories

[Product Name] Customized abutment and accessories

[Structure and Composition] Composed of customized abutment, central screw, customized healing abutment, and cover screw, the material is made of titanium alloy (TC4ELI) processed by CAD/CAM. The interface size of the abutment is fixed, and the screw size is fixed. The gingival GH, abutment diameter D1, abutment height AH, and angle β of the upper part of the abutment can be customized designed and processed. The gingival portion GH and abutment diameter D1 of the healing abutment can be customized processed. The surface of the customized abutment and accessories that have been cut, polished, and polished has not undergone any other treatment and is not sterile.

[Scope of Application] This product is a matched component for dental implants implanted in the jawbone after tooth loss, used to connect, support, and secure the upper structure of restorations or implants.

[Specifications and Types]

The specific Type of customized Platform is shown in the following table:

Connected method	Type	Customized processing range	Tightening Torque (Ncm)	Matching screw Type
Inner Triangle	CA01-01	D1：（4.0-5.0）±0. 1mm GH：（0.75-3.75）±0. 1mm AH：（4.0-6.0）±0. 1mm β：（0-23）±1°	25	AS01-01
	CA01-02	D1：（5.3）±0. 1mm GH：（1.0-3.0）±0. 1mm （1.8-4.5）±0. 1mm AH：（4.0-8.4）±0. 1mm β：（0-20）±1°	20	AS01-02
	CA01-03	D1：（5.8）±0. 1mm GH：（1.0-3.0）±0. 1mm （1.8-4.5）±0. 1mm AH：（4.0-8.4）±0. 1mm β：（0-20）±1°	20	AS01-02
	CA01-04	D1：（6.5）±0. 1mm GH：（1.0-3.0）±0. 1mm （1.8-4.5）±0. 1mm AH：（4.0-8.6）±0. 1mm β ：（0-20）±1°	20	AS01-03

Cross lock	CA02-01	D1：（4.3）±0. 1mm GH：（2.0-3.5）±0. 1mm AH：（4.0-5.4）±0. 1mm β：（0-15）±1°	35	AS02-01
	CA02-02	D1：（6.5）±0. 1mm GH：（2.0-3.5）±0. 1mm AH：（4.0-7.4）±0. 1mm β：（0-15）±1°	35	AS02-02
Inner hexagon	CA03-01	D1：（4.5-6.5）±0. 1mm GH：（1.0-6. 1）±0. 1mm AH：（4.0）±0. 1mm	35	AS03-01
	CA03-02	D1：（4.5-5.5）±0. 1mm GH：（1.0-4.0）±0. 1mm AH：（4.0-8.8）±0. 1mm β：（0-25）±1°	30	AS03-02
	CA03-03	D1：（4.5）±0. 1mm GH：（2.0-4.0）±0. 1mm AH：（4.0-8.0）±0. 1mm β：（0-17）±1°	20	AS03-03
	CA03-04	D1：（5.0-6.0）±0. 1mm GH：（2.0-4.0）±0. 1mm AH：（4.0-8.0）±0. 1mm β：（0-17）±1°	30	AS03-04
	CA03-05	D1：（4.8）±0. 1mm GH：（1.5-3.0）±0. 1mm AH：（4.0-6.5）±0. 1mm β：（0-15）±1°	35	AS03-05
	CA03-06	D1：（5.0）±0. 1mm GH：（1.5-3.0）±0. 1mm AH：（4.0-6.5）±0. 1mm β：（0-15）±1°	35	AS03-06
Inner octagon	CA04-01	D1：（5.05-6.0）±0. 1mm AH：（4.0）±0. 1mm	35	AS04-01
Note: D1 represents the diameter of the abutment; GH represents gingival height; AH represents the repair height; β represents angle.				

The specific types of customized healing abutment and cover screw are shown in the table below:

Cover screw		Customized healing abutment		
Connected method	Type	Connection method	Type	Customized processing range
Taper	CS01-01	Taper	HA01-01	Gingival height GH:(0.75-2.50) ± 0.1mm Interface diameter D1: (2.70) ± 0.05mm
Platform	CS01-02	Platform	HA01-02	Gingival height GH:(4.00-6.00) ± 0.1mm Interface diameter D1: (3.80) ± 0.05mm
Platform	CS01-03	Platform	HA01-03	Gingival height GH:(4.00-6.00) ± 0.1mm Interface diameter D1: (4.30) ± 0.05mm
Platform	CS01-04	Platform	HA01-04	Gingival height GH:(4.0-6.0) ± 0.1mm Interface diameter D1: (5.00) ± 0.05mm
Taper	CS02-01	Taper	HA02-01	Gingival height GH:(2.0-5.0) ± 0.1mm Interface diameter D1: (2.78) ± 0.05mm
Taper	CS02-02	Taper	HA02-02	Gingival height GH:(2.0-6.0) ± 0.1mm Interface diameter D1: (3.30) ± 0.05mm
Platform	CS03-01	Taper	HA03-01	Gingival height GH:(2.3-6.6) ± 0.1mm Interface diameter D1: (3.08) ± 0.05mm
Platform	CS03-02	Taper	HA03-02	Gingival height GH:(3.5-5.0) ± 0.1mm Interface diameter D1: (3.33) ± 0.05mm
Platform	CS03-03	Taper	HA03-03	Gingival height GH:(3.0-5.0) ± 0.1mm Interface diameter D1: (2.78) ± 0.05mm
Platform	CS03-04	Taper	HA03-04	Gingival height GH:(3.0-5.0) ± 0.1mm Interface diameter D1: (3.30) ± 0.05mm
Platform	CS03-05	Taper	HA03-05	Gingival height GH:(3.0-5.0) ± 0.1mm Interface diameter D1: (2.95) ± 0.05mm
Platform	CS03-06	Taper	HA03-06	Gingival height GH:(3.0-5.0) ± 0.1mm Interface diameter D1: (3.34) ± 0.05mm
Taper	CS04-01	Taper	HA04-01	Gingival height GH:(2.0-4.5) ± 0.1mm Interface diameter D1: (4.79) ± 0.05mm

[Product Performance] The chemical composition of the customized abutment and accessories shall comply with the performance requirements of TC4ELI and titanium rod in GB / T13810-2017.

[Usage Method]

1. Prepare before use

Confirm the expiration date and opening status on the packaging, and check if it has expired or been opened. Fully master its usage method before use. Conduct comprehensive and oral examinations for surgical patients and develop treatment plans.

2. How to use it

After the alveolar bone heals, remove the cover screw/healing abutment from the dental implant. Install the matching customized abutment, connect the central screw to the dental implant and abutment, and tighten with a torque wrench. Before tightening the screw, ensure that the abutment is correctly positioned on the implant. Suitable prosthetic restoration devices such as dentures can be installed on customized abutments.

[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 for 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, pregnant women, poor oral hygiene.

[Warn]

We strongly recommend that our company's products be used by experienced operators or dentists who have received training in dental implant systems.

Before using unsterilized products: The base must be cleaned in a clean environment and subjected to high temperature, high pressure disinfection, and sterilization before use.

The product and supporting special tools shall not be mixed with similar products from other manufacturers, and titanium alloy and stainless steel materials shall not be mixed.

This product is disposable and should be disposed of after removal. It cannot be reused.

This product is used in combination with porcelain crowns, all ceramic crowns, and other dental crowns for repairing the upper part of the base. The screw or adhesive fixation should be firm.

Medical device waste shall be disposed of in accordance with the Regulations on the Management of Medical Waste.

[Precautions]

1. General precautions

1) Dental implant surgery is a highly specialized and complex process. Operators must undergo formal training before performing implantation surgery.

2) Principles of treatment plan

Surgical procedures need to be carried out based on a comprehensive assessment of the patient, preoperative diagnosis, and treatment plan.

Warning: Errors in patient evaluation, preoperative diagnosis, and treatment planning may result in implant failure.

3) Selection criteria/indications

Local and global contraindication analysis: normal wound healing ability, effective oral hygiene/completely healthy remaining teeth, fully grown upper and lower jaws, good treatment conditions, and sufficient jawbone mass.

4) Precautions for Local Inspection

The anatomical morphology of the alveolar ridge, the relationship between the internal maxilla, and deep occlusion. The quality and thickness of mucous membranes, research models, bite records X-ray fluoroscopy.

Before clinical use, doctors should fully understand the physiological and psychological limitations of patients using this product, and make patients aware of the risks and potential adverse factors of surgery.

2. Precautions before surgery

1) Before use, the packaging status of the product should be confirmed, and products with damaged or opened packaging should not be used;

2) Before use, the name, type, and size of the product should be confirmed;

3) Products with expiration dates shall not be used;

4) This product needs to be used in conjunction with matching implants and surgical tools;

5) Must be used by professional doctors or technicians;

6) The manufacturer shall not be held responsible for the use of products with expiration dates specified for re sterilization by users.

3. Precautions during surgery

1) All tools used in the operation must be in good condition at all times.

2) The components of the abutment system are very small, please ensure that they are not accidentally swallowed or inhaled by patients.

3) When placing the abutment system and implants, they must be tilted at an angle of 30 ° or higher. More careful attention should be paid to prevent the abutment system and the matching implant from being broken, and immediate loading of the fixed abutment after surgery should be avoided.

4. Patient precautions

Keep your mouth completely clean. Do not apply excessive pressure to the teeth until the final dentures are in place.

[Product Maintenance and Maintenance Methods]

The customized abutment and accessories are all non sterile packaging. Before placing it in the patient's mouth, the product must be cleaned, disinfected, and sterilized. For the abutment, it is recommended to clean, disinfect, and sterilize it according to the following recommended methods in WS 310.2 or use other suitable methods before use.

1) Use mechanical cleaning (such as ultrasonic cleaning equipment) or manual cleaning;

2) The sterilization recommendations are as follows:

Use a lower exhaust steam pressure sterilizer for sterilization, with a sterilization temperature of 121 ℃, a sterilization time of 20 minutes, and a sterilization pressure ranging from 102.8 kPa to 122.9 kPa.

[Production Date]

See label

[Validity Period]

Not applicable

[Medical Device Registration Certificate Number/Product Technical Requirement Number]

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