Instructions For Use

TruBase

Authorization

	Prepare	Approval
Signature		
Date(DD-MM-YEAR)	27/NOV/2023	27/NOV/2023
Function/ Name	R&D / Seunghwa lee	R&D / Haengoh Kim

Contents

This document contains the following sections:

0. REVISION HISTORY

Revision Number	Effective Date (yyyy-mm-dd)	Reason for Change
0	20-MAY-2016	Initial established.
1	17-MAR-2022	Modify General Description, How to use the product, End-user Sterilization Information, Warning, Labeling symbols.
2	22-NOV-2023	As K213961 was completed, Astra EV, BioHorizon, Osstem, Straumann Tissue level were added. MR conditional label symbol update.
3	27-NOV-2023	The sterilization symbol has been deleted.

1. INSTRUCTIONS FOR USE

Instructions For Use

General Description

TruBase consists of a two-piece abutment, where the titanium base is a pre-manufactured abutment that will be used to support a CAD/CAM designed superstructure (the second part of the two-piece abutment) that composes the final abutment.

TruBase abutments are made of titanium alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications and are provided in various prosthetic platform diameters.

The CAD/CAM patient-specific superstructure that composes the final abutment is intended to be sent to a TruAbutment-validated milling center to be designed and milled, according to the prosthetic planning and patient clinical situation. The superstructure is cemented to the TruBase in the lab. Use “RelyX Unicem 2Automix” as an adhesive extra orally to connect.

TruBase is provided non-sterile therefore must be sterilized after the cementation of the patient-specific superstructure on the TruBase.

The TruBase is a device that can only be sold, distributed, or used upon the order of an authorized healthcare provider, generally referred to as prescription (Rx) devices.

Indication for Use

The TruBase is a titanium component that is directly connected to endosseous dental implants to provide support for patient-specific prosthetic restorations, such as copings or crowns. It is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the following systems:

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
Astra Tech OsseoSpeed TX (K024111)	3.0 S	11, 13, 15	3.0 (X-small)	Internal double Hexagon
	3.5 S	8, 9, 11, 13, 15, 17	3.5/4.0 (Small)	
	4.0 S			
	4.5	9, 11, 13, 15, 17	4.5/5.0 (Large)	
	5.0			
	5.0 S			
Dentium SuperLine (K160828)	3.4	8, 10, 12, 14	Regular	Internal Hex
	3.8			
	4.3			
	4.8			
	4.8	8, 10, 12		
	5.8			
Keystone Primaconnex (K051614)	3.5	10, 11.5, 13, 15	3.5 (SD)	Internal TiLobe
	4.1		4.1(RD)	
	5.0		5.0 (WD)	
MegaGen Xpeed AnyRidge (K140091)	3.5	7, 8, 10, 11.5, 13, 15, 18	3.5	Internal Hex
	4.0			
	4.5			
	5.0			
	5.5			
MIS C1 (K172505, K112162)	3.3	10, 11.5, 13, 16	NP	Conical connection
	3.8	8, 10, 11.5, 13, 16	SP	
	4.2			
	5.0		WP	
Neodent GM (K163194, K180536)	3.5	8, 10, 11.5, 13, 16, 18	3.0	Grand Morse connection
	3.8			
	4.0			
	4.3			
	5.0			
	6.0	8, 10, 11.5, 13		
NobelActive 3.0 (K102436)	3.0	10, 11.5, 13, 15	3.0	Internal Hex
	3.5		NP	Internal Hex

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
NobelActive Internal Connection (K071370)	4.3	8.5, 10, 11.5, 13, 15, 18	RP	
	5.0		RP	
	5.5	7, 8.5, 10, 11.5, 13, 15	WP	
NobelReplace Tapered (K050258, K050705, K062566, K023113)	3.5	8, 10, 11.5, 13, 16	NP	Internal tri-channel connection
	4.3		RP	
	5.0		WP	
	6.0		6.0	
Straumann BLX (K173961, K181703, K191256)	3.5	8, 10, 12, 14, 16, 18	RB	TorcFit connection
	3.8	6, 8, 10 ,12, 14, 16, 18		
	4.0			
	4.5			
	5.0			
	5.5	6, 8, 10, 12		
	6.5			
Straumann Bone Level (K162890)	2.9	10, 12, 14	SC	Internal Cross Fit
Straumann Bone Level (K140878)	3.3	8, 10, 12, 14, 16, 18	NC	
	4.1		RC	
	4.8			
Zimmer 3.1 (K142082)	3.1	8, 10, 11.5, 13, 16	2.9	Internal Hex
Zimmer Screw Vent and Tapered Screw Vent (K013227)	3.7	8, 10, 11.5, 13, 16	3.5	Internal Hex
	4.1		3.5	
	4.7		4.5	
	6.0		5.7	
OSSTEM TSIII SA (K121995)	3.5 (3.7)	8.5, 10, 11.5, 13	2.1 (Mini)	Internal Hex
	4.0 (4.2)	7, 8.5, 10, 11.5, 13	2.5 (Regular)	
	4.5 (4.6)			
	5.0 (5.1)			
	6.0 (6.0)			
	7.0 (6.8)			
Astra OsseoSpeed EV (K120414)	3.6	6, 8, 9,11 ,13, 15, 17	3.6	Internal Spline
	4.2		4.2	
	4.8		4.8	

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
	5.4	6, 8, 9,11 ,13, 15	5.4	
BioHorizons Tapered Internal (K093321, K143022, K071638)	3.0	10.5, 12, 15	3.0	Internal Hex
	3.4	9, 10.5, 12, 15, 18	3.4	
	3.8	9, 10.5, 12, 15, 18	3.5	
	4.6	7.5, 9, 10.5, 12, 15, 18	4.5	
	5.8		5.7	
Straumann Tissue Level (K122855, K202942)	4.1	6, 8, 10, 12, 14	Regular Neck (RN)	Internal Octagon
	4.8			
	4.8	6, 8, 10, 12	Wide Neck (WN)	

Cautions before use

1) Abutment is a prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

2) Before using the product clinically, dentists must fully familiarize themselves with the product and obtain full informed consent from the patient by reviewing both advantages and limitations of implants. For their part, patients must clearly understand the function and aesthetical limitations of implants.

3) We are under no obligation to replace our products or give a refund in case any defect or problems arise from the use of non-TruAbutment products (i.e. using our abutments with different screws).

4) Since the design of abutments is an important factor affecting the service life of the dental prosthesis, it is imperative that the design of the abutment has been reviewed prior to submission for milling. In the case that TruAbutment does the designing, the responsibility lies with the Dental Laboratory to request and review the design(s) for approval. If no such request is received, it will be considered an implied consent to proceed to milling.

5) Before selecting an abutment for a patient, their oral condition must be checked. A restorative plan is to be established based on thorough analysis.

6) Once the product has been used on a patient, all efforts should be made to prevent the patient from aspirating or ingesting the product.

How to use the product

1) After osseointegration has been successfully achieved for the fixture, design an appropriate CAD/CAM patient-specific abutment suitable to the oral environment.

2) Reproduce the configuration of the oral cavity of the patient through impression taking and send the impression to a dental laboratory to fabricate the final prosthesis. Once the final prosthesis fabrication is completed, deliver it to the patient to improve their masticating and aesthetic functions.

3) When affixing an abutment onto a fixture, the recommended torque value is equivalent to the manufacturers' value for the respective implant system. The torque value should be determined based on the clinical assessment of the bone quality, fixture dimensions, and prosthesis type, etc.

Compatible with Brand	Platform Size	Common Torque (Ncm)	ASC Torque (Ncm)
Dentsply sirona Astra Tech OsseoSpeed TX	3	15	15
	3.5~4.0	20	20
	4.5~5.0	25	25
Dentium SuperLine	Regular	30	25
Keystone Dental Prima/Genesis	3.5~5.0	30	25
MegaGen Xpeed AnyRidge	3.5	30	25
MIS C1	NP~WP	30	25
Neodent GM	3	25	25
NobelActive	3	15	15
	3.5~5.5	35	25
NobelReplace	NP~6.0	35	25
Straumann BLX	RB,WB	35	25
Straumann Bone Level	SC	25	25
	NC,RC	35	25
Zimmer Eztetic 3.1	2.9	30	25
Zimmer Tapered Screw-Vent	3.5~5.7	30	25
Osttem TSIII	Mini	20	20
	Regular	30	25
Astra OsseoSpeed EV	3.6~5.4	25	25
BioHorizon Tapered Internal	3.0~5.7	30	25
Straumann Tissue Level	RN,WN	35	25

Cautions when using the product

1) The product must be used by an appropriately trained professional. Damaged tools should not be used. Arbitrarily changing or modifying the product is not-recommended and will void the lifetime warranty of the abutments.

2) Prior to fabrication and delivery of prosthesis, confirm osseointegration of the implants by utilizing X-ray imaging and percussion testing.

3) A working model is produced after obtaining impressions. The working model should be carefully utilized during the laboratory process, together with the appropriate prosthetic components, in order to achieve functional occlusal surfaces between the upper and lower jaw.

4) Temporary prosthesis should be carefully adjusted for the condition of the patient's oral cavity, especially until the implants prove to be osseointegrated.

5) No cement should be applied to the Morse taper area between fixtures and abutments.

Risks and Side Effects

Below is a list of conditions that bear higher risks of implant surgeries but specialists should examine the patient case by case and plan accordingly.

1) Metabolic disorders such as diabetes and etc.

2) Endocrine disorders such as hypothyroidism, hyperthyroidism, adrenal gland disorders, and etc.

3) Circulatory disorders such as angina pectoris, myocardial infarction, congestive heart failure, chronic valvular heart disease, high and low blood pressure, and etc.

4) Respiratory disorders such as asthma and etc.

5) Kidney and blood-related disorders.

6) Bone disorders such as osteoporosis, osteomalacia, Behcet's disease, and etc.

7) Collagen disease.

Contraindications

1) Severe intraoral infections.

2) Impacted tooth, cysts, tumors, etc.

3) Unclear medical history.

4) Lack of alveolar bone.

5) Poor health of alveolar bone (i.e. osteoporosis, osteomalacia, and Behcet's disease).

6) Not enough space of alveolus membrane.

7) Unhealthy adjacent tooth.

8) Do not use these components if the patient has a known hypersensitivity to titanium, titanium alloy.

Proper storage and care

After sterilization, place the devices in a dry dark place such as a closed cupboard or drawer. Follow the instructions of the manufacturer of the FDA-cleared pouches regarding storage conditions and expiration date of sterilized goods.

End-user Sterilization Information

TruBase is for one-time use only and provided non-sterile therefore must be sterilized prior to use. All TruBase components are cleaned using multiple sessions of ultrasonic baths to remove contaminants from the milling process.

1. First session

Immerse finished products into trichloroethylene at 30º C (86º F), running the process for 15 minutes.

2. Second session

Immerse products into ethanol at 30º C (86º F), running the process for 15 minutes.

3. Third session

Immerse products into distilled water at 30º C (86º F), running the process for 15 minutes.

4. Place cleaned products into a dryer then run at 120º C (248ºF) for 10 minutes using hot air.

Rinsing:

Whether mechanical or manual cleaning has been performed, the device should be thoroughly rinsed to ensure that loosened debris and detergents are adequately removed. Tap water can be used for rinsing to ensure that copious volumes are used but since the quality of tap water varies considerably by region, the final rinse should be performed with treated water that is of a quality that does not contribute to staining or contamination.

Recommended validated sterilization parameters for wrapped devices:

Method	Moist heat sterilization
Cycle	Pre-vacuum
Temperature	270ºF (132ºC)
Exposure time	4 minutes
Drying time	20 minutes in chamber

(Source: ANSI/AAMI ST79 Table 5)

Wraps made by Kimberly-Clark Corp is used during sterilization.
All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance with EN 285/EN 13060, EN ISO 17665, ANSI AAMI ST79.
According to EN ISO 17665, the final responsibility for validation of cleaning, disinfection and sterilization techniques and equipment lies directly with the end user. To ensure optimal processing, all cycles and methods should be validated.

Storage

Follow the instructions of the manufacturer of the FDA-cleared pouches regarding storage conditions and expiration date of sterilized goods.

Warning

The TruBase has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of TruBase in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. Federal law restricts the sale of this device to or on the order of licensed dentists.

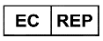
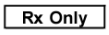
Rx Only

Caution : U.S. Federal law restricts these devices for sale, distribution and use by, or on the order of, a dentist or physician

Labeling symbols

Symbols may be used on some international package labeling for easy identification.

	Do not re-use
	Use-by date
	Batch code
	Date of manufacture
	Catalogue number

	Do not resterilize
	Keep away from sunlight
	Caution
	Manufacturer
	Consult instructions for use
	Authorized representative in the European Community
	Notified Body Number
	Do not use if package is damaged
	Prescription only
	Keep dry
	Temperature limit
	Medical device
	MR Conditional

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