Instructions for use

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Dental Implant, Abutments, URIS OMNI System & Prosthetics
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TruAbutment Korea Co., Ltd.
#214, 215, 216, 104-dong, Seokcheon-ro 397,
Ojeoung-gu, Bucheon-si, Gyeonggi-do, Korea
Phone: +82 (32) 678 4688
Fax: +82 (32) 624 4689
www.truabutment.com
www.urisimplants.com

Device Description

URIS OMNI Narrow System fixtures are dental implants made of Unalloyed Titanium, grade 4 (ASTM F67) intended for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors. The surface is SLA (Sandblasted, Large grit and Acid etched) treated and is provided sterile. It consists of two implant lines, the OMNI and the OMNI Tapered, with corresponding cover screws, healing abutments and prosthetic abutments. The OMNI Tapered implant has a tapered wall with a single thread design. The OMNI implant has straight wall with smaller threading at the coronal end, and bigger threading at the apical end. Both implant lines have Narrow (Ø 3.15 mm) platform sizes. Both implant lines share the following diameters and lengths.

Ø 3.15 x 10, 11.5, 13, 14.5mm (L)

URIS Prosthetic System is made of titanium alloy (Ti-6Al-4V ELI) intended for use as an aid in prosthetic restoration. It consists of Ball Abutment, Retainer Cap, Retainer, T LOC Straight Abutment, T Loc Titanium Cap, Multi-Unit Straight Abutment, Multi-Unit Angled Abutment, Multi-Unit Healing Cap, Multi-Unit Ti Cylinder, Multi-unit temporary cylinder, Multi-Unit Base, Multi-Unit Cylinder screw, URIS DS, URIS Base. No additional angulation is to be included in the when using a coping or cylinder (i.e., Multi-unit Ti Cylinder, Multi-unit Temporary Cylinder, Multi-unit Base) with any of the Multi-unit Abutments.

Cover screw and healing abutment are anodized in yellow or green.

Device Component	Diameters (Ø)	Lengths	Angulation
OMNI Fixtures	3.15mm	10~14.5mm	
OMNI Tapered Fixtures	3.15mm	10~14.5mm	
Ball Abutments	3.5mm	Cuff Height: 1.0~6.0mm	
Retainer Cap	5.1mm	3.9mm	
Retainer	5.1mm	2.1mm	
TLOC Straight Abutments	3.8mm	Cuff Height: 1.0~6.0mm	
TLOC Titanium Cap	5.4mm	2.3mm	
Multi-Unit Straight Abutments	5.0mm	Cuff Height: 1.0mm~6.0mm	
Multi-Unit Angled Abutments		Cuff Height: 3.0mm~5.0mm	17°
		Cuff Height: 4.0mm~6.0mm	29.5°
Multi-Unit Healing Cap	5.1mm	4.5mm	
Multi-Unit Ti Cylinder	5.0mm	5.0mm	
Multi-unit temporary Cylinder	5.0mm	12mm	
Multi-Unit Base	5.0mm	4.35/7.35mm	
Multi-unit Cylinder screw	1.6mm	3.3mm	
URIS DS	Ø3.8~ Ø 5.5mm	6~11mm	0~25°
URIS Base	4.0mm/4.3mm	Cuff Height: 1.0/2.0mm	

Fixtures and cover screw are provided sterile and other prosthetics are provided non-sterile. All non-sterile products must be sterilized by end users before use.

URIS Base 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. URIS Base is made of titanium alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications. It is compatible with the following systems:

URIS Base is provided non-sterile therefore must be sterilized after the cementation of the zirconia superstructure on the URIS Base.

Design Limitation for Zirconia superstructure

Design parameter	Design Limit
Minimum and Maximum abutment angle	0~15
Minimum and Maximum Cuff Height	0.5~5 mm
Minimum and Maximum diameter at abutment/implant interface	5.0mm~ 8.0mm
Minimum Thickness	0.4 mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4 ~6 mm

Design Limitation for URIS DS

Design parameter	Design Limit
Minimum and Maximum Gingival Height	0.5~4mm
Minimum and Maximum diameter at abutment / implant interface	3.8~ 5.5
Minimum and Maximum length of abutment	6~11mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4~8mm
Minimum wall thickness at abutment / implant interface	0.4mm
Minimum and Maximum abutment angle	0~25º

INDICATIONS FOR USE

URIS OMNI Narrow System & Prosthetic is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

RESTORATIVE COMPONENTS:

1. ABUTMENTS

The abutments are used to restore a dental implant, acting like the base for the prosthesis. They are available in different shapes and sizes to respond to different needs. It should maintain at least 4mm from the abutment platform to avoid damaging the abutment screw:

Titanium Abutments

There are five types of titanium abutments available:
- Ball Abutment: Ball abutment is a type of extra coronal attachment mechanism used with dental

Implants to retain an overdenture.
- TLOC Straight Abutment: T Loc Straight Abutment allows to have a low profile, i.e. low vertical height, they may be used for all types of removable complete dentures.
- Multi-unit Abutment: Multi-Unit abutment is used for screw-retained bridges and full-arch restorations. Straight and angulated Multi-Units are available. Abutments with a post length of less than 4mm is only available for multi-unit cases.
- URIS DS: URIS DS is designed and produced specifically for the patient using CAD/CAM technology taking into account the angle of the implant applied to the patient. Abutments with a post length of less than 4mm is only available for multi-unit cases.
- URIS Base: URIS Base are products which are used for the digital acquisition of an implant position and for the restorative supply of implants. The URIS Base product comprises two individual
- Components: Titanium base and Abutment Screw. Abutments with a post length of less than 4mm is only available for multi-unit cases.

2. SCREWS
The screws are made from Ti-6Al-4V ELI(ASTM F136), recommended for its biocompatibility, its mechanical strength and hardness. It serves to attach the abutment or prosthesis to the implant (clinical screw) or to the laboratory analogue (laboratory screw).

RECOMMENDATIONS FOR ITS SPECIFIC USE INCLUDE:
The screws are for single-use only. It is not recommended to use the screws again after their removal, not even in the laboratory, due to the possible deterioration of their behavior. It is vitally important to not use clinical case screws that have been previously used in a dental laboratory.
It is important to verify the compatibility of the implant model to be used. You should avoid causing any damage around the area where the implant is connected, so care must be taken if carving or machining in this area. Radiography is recommended in the height of the junction of the union with the perpendicular axis of said union, once the implant is fixed, for verification.

Torque
Only the implant manufacturer's recommended torque is to be used.

Ncm	Abutments (Narrow Connection)
20	Ball Abutments, Multi-Unit Angled Abutments, Multi-Unit Straight Abutments, TLOC Straight Abutments, URIS DS, URIS Base.

Ncm	Abutments (Regular Connection)
30	Ball Abutments, Multi-Unit Angled Abutments, Multi-Unit Straight Abutments, TLOC Straight Abutments, URIS DS, URIS Base.

Ncm	Components
20	Multi-Unit Temporary Cylinder, Multi-Unit Ti Cylinder, Multi-Unit Base.

Warnings:
The instructions given are insufficient if used as the only reference for the use of the cited components. These elements should only be inserted by dentists who have been fully trained in the insertion of dental implants. The use of these products without any prior specific knowledge can lead to component failure and may require implant removal. The safety of our products is guaranteed only when they are used exclusively by trained professionals. Read the instructions carefully on the labels of the products, where you will find the basic guidelines. Keep a record of the products used in the patient's personal medical booklet, stating the name of the product, the reference number, and the lot number. Please inform URIS Implants of any defects or complications related to any of its products. All URIS OMNI Narrow System products are solely for single use. To reuse the single-use products may lead to a possible deterioration of the characteristics of the product, which in turn can lead to an elevated risk in gum or tissue infection and deterioration in the patient's health. In general, implant component's placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered. There is a risk of accidental inhalation and/or ingestion of the products when they are used, therefore it is necessary to carefully hold onto the products in case of intraoral applications. The patient should be made aware of any limitations in his/her treatment, and the need for maintenance, for example, the need to seek medical assistance if any symptoms or side effects arise. It should be recommended to the patient to conduct regular dental check-ups for maintenance of the URIS OMNI Narrow System products. The products are not sterilized when sold, and therefore, it is recommended to clean and sterilize the products before their use.

* Warning: Small diameter implants and angled abutments are not recommended for the molar region of the mouth.

Contraindications:
It is contraindicated placing dental implants in patients:
- Medically unfit for an oral surgical procedure
- With inadequate bone volume unless an augmentation procedure can be considered
- In whom adequate sizes, numbers or desirable position of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Allergic or hypersensitive to titanium alloy (grade 5).

MR Statement
The URIS OMNI System 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 URIS OMNI System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

End-User Sterilization Information
All prosthetic abutments are provided non-sterile and must be sterilized before use. To correctly sterilize the products, use a steam sterilizer with pre-vacuum process, at a temperature of steam sterilizer at 132° C for 4 minutes, wrap and dry 20 minutes with a validated cycle according to the standard ISO 17665 1 following the autoclave manufacturer instructions.

	Pre-Vacuum Autoclave
Temperature	132° C
Exposure Time	4 minutes
Dry Time	20 minutes

Note: The validated procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79.

Storage
The product has to be stored in its original package in a dry place at room temperature.

LABELING SYMBOLS

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

	Do not reuse
	Use by date
LOT	Batch code
	Date of manufacture
	Non-Sterile
REF	Catalogue number
	Caution, consult accompanying documents
	Manufacturer
	Consult instructions for use
	Do not use if package is damaged
Rx Only	Prescription only

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