Instructions for use

EN

Dental Implant, Abutments, URIS OMNI System
Valid only in United States
IFU_UOI0005, Revison 02, Document valid as of May-4-2018

2 — 4

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 System fixtures are dental implants made of Unalloyed Titanium, grade 4 (ASTM F67) intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations. 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 is straight walled with smaller threading at the coronal end, and bigger threading at the apical end. Both implant lines have two platform sizes, Narrow (Ø 3.5 mm) and Regular (Ø 4.0 – Ø 6.5 mm). Both implant lines share the following diameters and lengths:

Ø 3.5 x 8.5, 10, 11.5, 13, 14.5mm (L)
Ø 4.0 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
Ø 4.5 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
Ø 5.0 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
Ø 5.5 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
Ø 6.0 x 7, 8.5, 10mm (L)
Ø 6.5 x 7, 8.5, 10mm (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 Cover screw, Healing abutment, Direct Abutment, Basic abutment, Angled abutment, Milling abutment, Temporary abutment, and Abutment screw. The surface of cover screw and healing abutment are anodized in yellow and green.

Device Component	Diameters (Ø)	Lengths	Angulation
Cover Screw	2.78/3.48mm	4.875/5.375mm	-
Healing Abutments	4.0/4.5/5.5/6.5/7.5mm	Cuff Height: 1.0mm~5.0mm	-
Direct Abutment	4.0/4.5/5.5/6.5mm	Cuff Height: 1.0mm~6.0mm	-
Basic abutment	4.0/4.5/5.5/6.5mm	Cuff Height: 1.0mm~6.0mm	-
Angled abutment	4.0/ 4.5/5.5mm	Cuff Height: 2.0mm~5.0mm	17°
Milling abutment	4.0/5.0/6.0/7.0mm	Hex Type: 14.1/14.85mm Non-Hex Type: 13.9/14.85mm	-
Temporary abutment	3.7 / 4.3mm	Cuff Height: 1.0mm~3.0mm	-
Abutment screw	1.9/2.3mm	7.2/7.7mm	-

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.

Indications for Use

URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillae, 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 four types of titanium abutments available:
  - Basic Abutments: None of the Basic abutments are to be used as titanium base abutments or as part of a hybrid abutment (e.g. part of a two-piece abutment). Basic abutments are full size abutments and are to be used straight. No angular correction or divergence is allowed by any additional copings, or modifications.
  - Angled Abutments: In general, they are angled at 17º, which can be adapted to the majority of clinical cases.
  - Milling Abutments: Intended to be milled by hand and are intended to be used straight. No angular correction or divergence is allowed.
  - Temporary Abutments: Intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement-retained restorations. Maximum duration for use of Temporary Abutment is less than six months. Temporary restorations should be out of occlusion.

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)
5~10	Cover Screw, Healing Abutment,
20	Basic Abutment, Direct Abutment, Angled Abutment, Milling Abutment, Temporary Abutment

Ncm	Abutments (Narrow Connection)
5~10	Cover Screw, Healing Abutment,
20	Temporary Abutment
30	Basic Abutment, Direct Abutment, Angled Abutment, Milling Abutment, TruBase

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

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