Instructions for use

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Dental Implant, Fixtures, URIS OMNI System
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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.
Instructions for operation and use

A. Preparation before use

1) Before clinical use, the clinician must be well acquainted with the surgical procedure of the product, and has to inform the patient about the limitations of the implant system. The patient should also be well aware of any functional and aesthetic limitations of the implant.
2) Because proper selection and fixation of the implant are closely related to the life-span of the implant, the clinician must follow the indications, contraindication, cautions and recommendations.
3) Handling procedures must be followed in order to prevent potential damage to the implant. Damage to the implant and/or patient may occur without careful review of the patient's condition and establishment of proper diagnosis and restorative plans.
4) The clinician must select the appropriate device based on careful review of the patient's X-ray picture and overall condition.
5) Check the products' expiration date and condition of the packaging for any visible damages.
6) Since the product is packaged aseptically, do not use if the packaging is damaged or torn.
7) Be sure to properly maintain the hygiene standards and preparatory state of the surgical instruments in order to prevent the use of contaminated instruments which may lead to complications and/or implant loss.
8) Inspect for any foreign-material before use.

B. Instructions and procedural sequence

During the diagnosis and planning, you must exclude any patient with local lesions or other contraindications and choose candidates who have proper bone condition to undergo implant surgery. Before proceeding to surgery, you must sterilize operation room and patient's oral cavity and perioral area thoroughly. After proper draping, perform local anesthesia and make an incision on the implant site and form a flap. Expose the implant site sufficiently and proceed to implant surgery.

(1) Implant site preparation
To implant the fixture, various drills are used in sequence for site preparation during osteotomy. To place the fixture accurately in the selected site, a hole must be made according to the size of the artificial dental prosthesis, using the respective instruments (drilling, tapping). Rotatory speed during these procedures must be adjusted taking the recipient bone condition and type of equipment used into consideration. The maximum permissible rotatory speed for the drill is generally 1,000~1,500rpm and 20~30rpm for the tap drill. The procedure should be performed using adequate normal saline to reduce the generation of heat on the bone tissue.

(2) Placing the fixture
Pick up the fixture from the sterile vial using the Fixture Driver and Adapter and place the fixture into the osteotomy. Install the fixture at low speed (25 rpm) under profuse irrigation and the maximum torque set at 45 Ncm. Allow the implant to work its way into the osteotomy. Avoid applying unnecessary pressure.

NOTE: The final recommended torque at seating should be 20~40Ncm for the URIS OMNI System.
Excessively high insertion torque may cause necrosis of the peri-implant bone in the receiving site which may result in implant failure.

(3) Inserting the cover screw
After the fixture has been placed, attach the cover screw using a driver below 10Ncm torque. Make sure there are no foreign bodies inside and suture the operation site.

(4) Connecting the abutment
Osseo-integration of the fixture requires 3~4 months for the mandible and 6~8 months for the maxilla. After this period, expose the implant and connect the healing abutment to enhance mucosal healing.

(5) Prosthesis attachment
After a healing period of between 2~4 weeks, connect the impression post to obtain an impression and manufacture a dental mockup. Deliver the final prosthesis.

Cautions

(1) Cautions during use

1) The operation must be performed by a well-trained, qualified dental specialist.
2) While performing the osteotomy, you must follow the procedure outlined in the catalog and the fixture should be adequately implanted.
3) Ensure that the soft tissue does not interfere with the connection between the fixture and prosthesis by verifying complete and proper seating.
4) All instruments and tooling used during the procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants and/or other components. Therefore inspect the condition of the instruments before every operation.
5) The product is provided sterile via gamma ray sterilization therefore it recommended to be opened prior to immediate use.
6) If the package has been damaged, discard the product since the aseptic condition has been compromised.

(2) Contraindications

1) Intraoral contraindications

A. In cases with insufficient bone tissue where severe bone resorption is predicted. Or if there is insufficient remaining bone for early-fusion in the proximal tooth extraction wound.
B. Disorder in mastication or functional relation
C. Pathologic condition of the alveolar bone
D. Prior radiotherapy on jawbone
E. Xerostomia
F. Pathologic change of oral mucosa (vitiligo, lichen planus, stomatitis)
G. Macroglossia
H. If vital anatomical structures are nearby
I. Cellulitis in surrounding soft tissues
J. If there are not sufficient soft tissues or its condition is poor

2) Transient contraindications

A. Acute inflammatory disease or infection
B. Pregnancy
C. Temporary effect of specific drugs (anticoagulant, immune-suppressant)
D. Mental, physical fatigue

3) Psychological contraindications

A. Poor compliance
B. Alcohol or other substance abuse
C. Neurosis, psychosis patient
D. Troublesome patient

4) General medical contraindications

A. General/nutritional condition - age (obesity, cachexia, 5year survival rate)
B. Current medications (corticosteroid, long-term antibiotic treatment)
C. Metabolic disorder (pubertal diabetes, overt hyperglycemia (>300mg/dl))
D. Hematologic disorder (disorder of RBC, WBC, coagulation)
E. Cardiovascular diseases (artherosclerosis, overt hypertension (>300mmHg))
F. Metabolic disorder of skeletal system (osteomalacia, Paget's disease, menopausal osteoporosis)
G. Connective tissue disease (dermatosclerosis, rheumatoid arthritis)
H. Implant as potential infection focus (prosthetic valve, bacterial endocarditis)

(3) Warnings

1) Implant operation should be performed by skilled dental surgeon because mishandled procedure may damage the implant or recipient bone
2) Implant is not to be recycled and it should be used for its original purpose
3) Damaged or mishandled implant should be removed
4) Inappropriate implant selection and improper implantation site or unstable fixation may shorten the life-span of the implant
5) Defective product should be withdrawn
6) Handle the implant carefully to prevent any damage or deformation
7) Warning: Small diameter implants and angled abutments are not recommended for the molar region of the mouth.

(4) POTENTIAL ADVERSE EFFECTS AND COMPLICATIONS

General complications after intraoral implant surgery include local hemorrhage, edema and hematoma. Transient loss of taste sense and masticatory function may occur. Additionally,
following complications may develop:

- Iatrogenic trauma of surrounding tissues (lower alveolar nerve injury or sensory change, injury or hemorrhage in maxillary sinus or nasal cavity)
- Insufficient or failed bony fusion
- Wound dehiscence on sutured site
- Delayed recovery, edema due to anesthesia
- Mucositis around implant due to insufficient adhesive soft tissue
- Incomplete implant placement due to insufficient bone removal or overt compression
- General hypersensitivity reaction

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.

Sterility

All dental implants (fixture) and cover screw are supplied sterile and are labeled “STERILE”. All products sold sterile are for single-use before the expiration date printed on the product label. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize.

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.

Handling

- This product is a disposable sterilized medical instrument and should therefore not be reused.
- Packing must be opened prior to surgery in a clean area.
- Discard if wrapping has been opened even if product is unused.
- Do not use the product, if the shelf life has expired.
- Opened products cannot be returned to the manufacturer or distributor.
- Manufacturer or distributor has no responsibility for products re-sterilized by users.

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

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