

Instruction for Use

Abutment

Indication for use

URIS Implant System – Superstructures which are placed into a dental implant to provide support for a prosthetic reconstruction. The URIS Implant System – Superstructures is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is used to secure the abutment to the endosseous implant.

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:

■ Titanium Abutments

There are two types of titanium abutments available:

- Straight Abutments: The base permits it to contour and adapt to the prosthesis. They are made from Ti-6Al-4V ELI (ASTM F136) to ensure maximum compatibility and durability.

- Angled Abutments: In general, they are angled at 17°, which can be adapted to the majority of clinical cases.

They are also made from Ti-6Al-4V ELI (ASTM F136), which increases the holding power of the cemented prosthesis.

Its straight base allows for a reduction in the vestibular surface, adapting itself to each clinical case.

■ Castable Abutments

The URIS Implant System castable abutment is made from medical POM plastic of outstanding casting quality, leaving no residues and does not create any voids.

These cylinders are used to prepare the final prosthesis on the implant: the corresponding castable abutment is made

by converting it to a metal cylinder selected by the laboratory. Compatible with the majority of implant connections, internal and external, and for the development of unitary solutions (non-rotating connection) or multiple solutions (rotating connections). The castable abutments are screwed to the replica of the implant with a screw,

using a screwdriver.

■ Multiunit Abutments

Multiunit Abutments that convert internal connections into a tapered external connection. It allows the lifting of the emergence profile and transforms the internal connections to the external connections to meet the requirements of special clinical cases. It is also made from Ti-6Al-4V ELI. It is available in several heights and angulations (in general,

from 1 to 5mm high, and in straight and angled types 17 and 29.5 degrees).

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.

3. Multiunit Healing Caps

The healing cap is placed on the implant, to protect it against masticatory stress during the osseointegration phase.

It is made from Ti-6Al-4V ELI (ASTM F136) and available in several heights for each implant system. Its height is defined by the distance that assures its correct functioning and avoids the transmission of tension from masticating.

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.

A 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

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Ncm	Abutments (Narrow Connection)
5~10	Cover Screw, Healing Abutment
20	Digital Mount, D Basis Abutment, Angled Abutment, Milling Abutment, Temporary Abutment, Multi Unit Abutment, Ball Abutment, Multi Unit Healing Cap, Multi Unit Cylinder

Ncm	Abutments (Regular Connection)
5~10	Cover Screw, Healing Abutment
20	Temporary Abutment, Multi Unit Healing Cap, Multi Unit Cylinder
30	Digital Mount, D Basis Abutment, Angled Abutment, Milling Abutment, Multi-Unit Abutment, Ball Abutment

Warnings and Contraindications

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 Trueabutment, Inc. of any defects or complications related to any of its products.

All URIS Implant 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.

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).

Warnings:

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 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 Implant System products.

The products are not sterilized when sold, and therefore, it is recommended to clean and sterilize the products before their use

MRI

URIS Implant System - Superstructure have not been evaluated for safety, compatibility, heating, or migration in the magnetic resonance (MR) environment

Sterility

The product is packaged cleaned, and should be sterilized before its 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, dry for 20 minutes with a validated cycle according to the standard ISO 17665-1 following the autoclave manufacturer instructions.

Storage

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

Labeling Symbols

Do Not Reuse



Use By Date



Batch Code



Date Of Manufacture



Sterilized Using Irradiation



Catalogue Number



Caution, consult accompanying documents



Manufacturer



Consult Instructions For Use



Do Not Use If Package Is Damaged



Prescription Only



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