Instructions For Use

A. UNIQA® Dental Implant System Instruction for Use

1. Product Description:

UNIQA Dental Implants System contains variety of types and sizes of specially designed bone-implantable titanium alloy Ti6Al4V Eli dental implants, dental abutments and dental instruments. Dental implants are surgically inserted into the upper and/or lower jawbone.

Dental Implants are provided sterile.

2. Indication for Use:

UNIQA® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

3. Intended Use:

UNIQA dental implants can be used for all indications requiring oral, endosseous implants for functional, aesthetic rehabilitation of edentulous and partially dentate upper or lower jaws. The restoration may comprise of single crowns, bridges and partial or full dentures connected to the implants with abutments.

4. Contraindications:

Severe uncontrollable systemic disease, metabolic bone disorders, uncontrolled hemorrhagic diseases, uncooperative/unmotivated patient, drug, alcohol or tobacco abuse, psychotic diseases, long standing, therapy-resistant functional disturbances, xerostomia, compromised immunoresistance and leucocytic malfunctioning, illnesses requiring periodic administration of steroids or anticonvulsant, allergic or hypersensitive to titanium Ti-6al-4v (titanium, aluminum, vanadium) , uncontrollable endocrine diseases. Relative contraindications: Previous bone radiotherapy, diabetes mellitus, medicinal anticoagulation / hemorrhagic diatheses, bruxism, parafunctional habits, complicated anatomical bone conditions, uncontrolled periodontitis, diseases of the temporomandibular joint, pathological diseases of the jaw and mucous membranes which can be treated, pregnancy, inadequate oral hygiene. Local contraindications: Insufficient bone and inadequate bone quality, local root debris or location of vital blood vessels, nerves, maxillary sinus, soft tissue space, and their relation to implant placement. Side-effects, interactions, and complications: Activities subjecting the body to increased physical stress should be avoided immediately after placement of dental implant. Complications associated with dental implants include, but are not limited to: Temporary complaints such as Pain, swelling, speech impediments, Gingival infections,

Inadequate function or device failure (mobility, loss of integrity), Injury during surgery, perforation (sinus, alveolar plates),post-surgical parathesia.

• Longer-term complaints:

Chronic pain related to the dental implant, permanent paresthesia, dyesthesia, loss of bone in the upper / lower ridges, Damage to existing dentition, local or systemic infections including bacterial endocarditis, oroantral fistulae, oronasal fistulae, adversely affected adjacent teeth, irreversible injury to adjacent teeth, fractured implant, jaw, bone, or restoration, problems with aesthetics, nerve damage, exfoliation, hyperplasia.

Complications associated with dental abutments include, but are not limited to: Inadequate function (incompatibility), Device failure(mobility, loss of integrity), Damage to existing dentition.

5. Warning:

Deficiencies in patient evaluation, pre-operative diagnosis and treatment planning may cause to implant failure or patient injury. Drilling beyond the depth intended from lower jaw surgery may potentially results in permanent numbness to the lower lip and chin or lead to a hemorrhage in the floor of the mount. Lack of adequate training of practitioner is major risk for patient health adequate training by certificate institute is necessary.

Periodic follow-up evaluations including radiographs are recommended. Special attention should be put on oral hygiene and habits, occlusion adjustments and the stability of the prosthesis.

6. Precautions:

Thorough screening of prospective implant candidates must be performed. Visual inspection as well as panoramic and periapical radiographs are essential to determine anatomical landmarks, occlusal conditions, periodontal status, and adequacy of bone. Lateral cephalometric radiographs, CT Scans, and tomograms may also be beneficial.

Special attention has to be given to patients who have localized or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g. evaluation of the dentition, cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphospohnate therapy.

In general, implant 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.

Use of the implant may require preoperative antibiotic prophylaxis. In type I or II bone when you feel strong a resistance at the time of placing the implant, remove the mount and place the insertion tool 2.5mm, rotate back (counterclockwise) 2-3 rounds then continue to screw clockwise. Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth. The maximum insertion torque is 45 Ncm.

The UNIQA Dental Implants 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 the UNIQA Dental Implants System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Dental Implants are provided Sterile and are for Single Use, do not re-sterilize and do not re-use! The implant is sterile unless the package is open or damage! Do not use product is the packaging has been damaged or previously opened!

7. Adverse Effects:

Loss of implant anchorage (failure to osseointegerate) and loss of the prosthesis are possible occurrences after surgery. Lack of quantity or quality of remaining bone, infections, poor patient oral hygiene or cooperation, and generalized diseases (diabetes, etc.) are some potential causes for loss of anchorage.

8. Surgical Complications:

The implant procedure has risks, including localized swelling, dehiscence, tenderness of short duration, edema, hematoma or bleeding. Numbness of the lower lip and chin region following lower jaw surgery and of the tissue beside the nose following upper jaw surgery, is a possible side-effect of the surgery. Though it would most probably be of a temporary nature, in very rare cases, the numbness has been permanent. Gingival-mucosal(gum tissue)ulceration, tissue reaction or infection may occur but generally responds to local care.

For information on surgical procedures, please consult UNIQA User Manual.

Recommended tightening limits:

- Implant installation for desired position use insertion torque max 45 Ncm. Do not exceed 45 Ncm.
- For immediate function, the implant should be able to withstand a final torque between 35-45 Ncm.
- The tightening of the abutment screw on the implant analog 10-15 Ncm.
- The tightening of the abutment screw on the implant 30 Ncm.
- The tightening of the healing abutment on the implant 5-10 Ncm.

9. Shipping, Handling and Storage

Implants and cover screws have been cleaned and sterilized by gamma irradiation and are ready to use. Sterile single packages contain: implant, implant mount, and cover screw; Dental Abutments are provided non sterile, prior to their used must be sterilized with accordance to the instructions. Dental Implants, abutments and accessories should be opened onto a sterile field.

The products must be stored in a dry place in the original packaging at room temperature air and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

10. Disposal

Product disposal shall be with accordance to local regulations and environmental requirements considering different contamination levels.

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2 Ha-Tsoran street, Netanya 4250602, Israel
Phone: 972-77-7827367 Www.Uniqa.Dental

CE **0483**

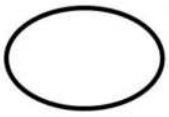
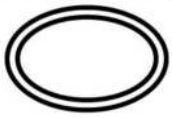
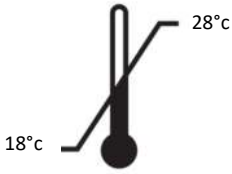
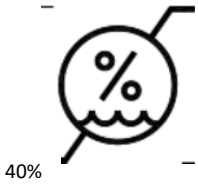
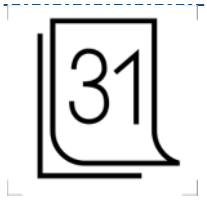
Prescription device: Rx Only
Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

EC REP Authorized European Representative: OBELIS S.A., Bd. Général Wahis, 53 , 1030 Brussels, Belgium
Tel: +32.2.732.59.54 Email: mail@obelis.net

Symbols Glossary:

The following symbols may be presented on the device labeling or/and accompanied information.

REF	Catalogue Number	LOT	Lot Number
	Use-by date		Do not use if package is damaged and consult instructions for use
	Consult instructions for use or consult electronic instructions for use		Caution
	Manufacturer Details	EC REP	Authorized Representative in the European Community
CE	CE Mark	MD	Medical device
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician or dentist.	UDI	Unique Device Identifier

	Date of manufacture		Non-pyrogenic
	Sterilized using irradiation		Non sterile
	Do not resterilize		Do not re-use
	Single sterile barrier system		Double sterile barrier system
	Single sterile barrier system with protective packaging inside		Single sterile barrier system with protective packaging outside
	Keep away from sunlight		Keep dry
	Temperature limit		Humidity limitation - Standard ambient condition
	Date		Information website for patients
	Patient Name or patient ID		Name and Address of the implanting healthcare institution/provider