SMART Israel Dental Solutions Implants System Instructions for Use

1. Product Description:

SMART Israel Dental Solutions Implants System contains variety of types and sizes of specially designed bone-implantable titanium alloy Ti6Al4V Eli dental implants, dental abutments and dental instruments. SMART Israel Dental Solutions Implants Design is a spiral tapered implant, self-drilling, self-tapping and self-condensing. SMART Israel Dental Solutions Implants are available in two options: (a) Conical 11° Connection Hex (b) Internal Hex Connection; The Dental Implants are available in two types of surface treatment (a) Pure & Porous, P&P - which consists of Hydroxyapatite and Calcium Phosphates Sand Blast Large Particles following acid etched; (b) SBA - Al2O3 Sand Blast Large Particles following acid etched;

Some products may not be regulatory cleared for sale in your market. Please contact your local sales representative.

SMART Israel Dental Solutions Implants Conical 11° Connection Hex

Platform	Implant Diameter	Length
Slim	Ø 3.0 mm	10, 11.5,13, 16 mm
MP	Ø 3.3 mm	8, 10, 11.5,13, 16 mm
RP	Ø 3.75 mm	8, 10, 11.5,13, 16 mm
RP	Ø 4.2 mm	8, 10, 11.5,13, 16 mm
RP	Ø 5.0 mm	10, 11.5,13, 15 mm

SMART Israel Dental Solutions Implants Internal Hex Connection

Platform	Implant Diameter	Length
MP	Ø 3.3 mm	8, 10, 11.5,13, 16 mm
RP	Ø 3.75 mm	8, 10, 11.5,13, 16 mm
RP	Ø 4.2 mm	8, 10, 11.5,13, 16 mm
RP	Ø 5.0 mm	8, 10, 11.5,13, 16 mm

Note: Dental Implants are provided sterile, for single use, with a cover screw. Opening packaging Instructions, Related Dental Instruments involved in the surgical procedure e.g. dental drills, depth probe, implant driver, screwdriver, ratchet. Drilling protocol is within *SMART* Surgical & Prosthetic Manual TF-MDR-1000-17.3 Surgical Prosthetic Manual. Processing of Dental Surgical Instruments Reusable refer to IFU TF-MDR-2000-17.1

2. Intended Use:

SMART 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.

3. Intended Users and Patient Groups

SMART medical devices are intended to be used by dental health care professionals.

SMART medical devices are intended to be used in partially and/or fully edentulous patients subject to dental implantation and/or restoration treatment.

4. Indication for Use:

SMART Israel Dental Solutions 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, to restore the patient's chewing function. SMART Israel Dental Solutions Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Conical Slim implants (Ø3.0mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.

5. Materials:

SMART Israel Dental Solutions Implants: Titanium alloy Ti-6Al-4V, Al2O3, Hydroxyapatite and Calcium Phosphates.

6. Contraindications:

Dental Implants System is contraindicated for:

Patients allergic or intolerance or hypersensitive to Titanium Ti-6Al-4V (titanium, aluminum, vanadium), Stainless Steel (Surgical Instruments, Dental Drills are with or without DLC Diamond Like Carbon).

Patients medically unfit for operation and/or surgical procedures: 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, 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.

7. Warning:

SMART Israel Dental Solutions Medical Devices are intended for use by trained dental specialists. It is recommended that practitioners attend hands-on training courses in order to learn proper techniques, including biomechanical requirements and radiographic evaluation.

To achieve the desirable performance, SMART's medical devices must be used with accordance to SMART's Surgical Prosthetic Manual (TF-MDR-1000-17.3), IFU Dental Surgical Instruments Reusable TF-MDR-2000-17.1.

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 if the packaging has been damaged or previously opened!

Dental Abutments, Healing Caps, Screws are provided non sterile and for single use, these must be sterilized before use with accordance to the IFU TF-MDR-1000-17.2.

Use of non-sterile device may lead to infection of tissues or infectious diseases.

For small size devices, components and detachable devices attention must be made to not swallow or aspirated by patient. Use your supporting medical devices to prevent aspiration or sallowness e.g throat shield.

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.

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.

8. 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.

9. 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.

10. Surgical Procedure:

Surgical procedures and drilling protocol are within SMART's Surgical Prosthetic Manual (TF-MDR-1000-17.3).

Tightening limits recommendations:

Implant installation for desired position use insertion torque max 50 Ncm. Do not exceed 50 Ncm.

For immediate function, the implant should be able to withstand a final torque between 35-45 Ncm.

The tightening of the healing abutment on the implant 5-10 Ncm.

The tightening of the abutment screw on the implant analog 10-15 Ncm.

The tightening of the abutment screw on the implant 30-35 Ncm.

11. Clinical Benefits and Undesirable Side Effects

Clinical Benefits associated with SMART Israel Dental Solutions Implants System and Instruments:

SMART Israel Dental Solutions Implants system consists of Implants, Abutments, screws, accessories and instruments being used with surgical implantation procedures and restorative application. The clinical benefits arising from these procedures are to restore missing teeth, restore missing crown and restoring patient chewing function.

Undesirable Side Effects associated with SMART Israel Dental Solutions Implants System and Instruments:

The surgical implantation procedure involves risks which may be associated with typical side effects such as localized swelling, infection, inflammation, tenderness of short duration, edema and 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.

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, bone fracture, perforation (sinus, alveolar plates),post-surgical parathesia.

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

During use of dental surgical instruments and implantation the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

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,

discoloration in the mucosal area, adversely affected adjacent teeth, irreversible injury to adjacent teeth, fractured implant, jaw, bone, or restoration, problems with aesthetics, nerve damage, exfoliation, hyperplasia.

Per European Medical Device Regulation MDR EU 2017/745 requirements SMART Summary of Safety and Clinical Performance SSCP is available for SMART Israel Dental Solutions Implants & Abutments at following website: https://ec.europe.eu/tools/eudamed .
(website available upon launch of the European Database on Medical Devices EUDAMED).

Serious Incident Notice

For a User/Patient/third party in the European Union and in countries having identical regulatory requirements, in the case of during use with this device or as results of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

12. Magnetic Resonance Imaging (MRI) – Safety Information

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

13. Storage, Handling and Transportation

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

14. Disposal

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

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

Distributor: SMART IMPLANTS TRADE LTD
Yakov Peri 13 Of.304, Rehovot 7639302, Israel
Phone: + 972-77-7827367 https://tz-trade.com/

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: ARAZY GROUP Gmbh.
The Squaire 12, Am Flughafen, 60549 Frankfurt am Main, Germany
Tel: +49 69 95932-5090 Email: Germany@Arazygroup.com

Basic UDI-ID Information:

Product	Basic UDI-ID Number
Dental Implants	729011285DentaImplantJX

Implant Card

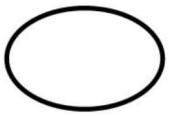
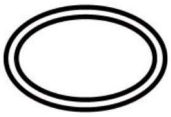
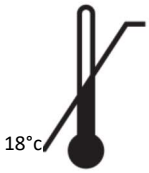
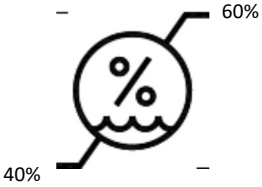
SMART Israel Dental Solutions Implants are provided with an Implant Card which contains important information for patients regarding the device. Complete the Implant Card by filling it with the patient and device identification information as indicated and provide the completed Implant Card to the patient.

Symbols Glossary:

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

	Catalogue Number		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		Authorized Representative in the European Community
	CE Mark		Medical device

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