ENGLISH

INSTRUCTIONS FOR USE

Read this entire instructions for use carefully before using the implants and components supplied by Titanimplant S.L.
The following instructions are aimed at qualified professionals, specialized in the field of dental implantology that had received the appropriate training.
The clinician must ensure that the selected product is suitable for the intended purposes and procedure.
The instructions for use are available on the following website: www.vulkanimplants.com/instructions-for-use

Product description

Vulkan® Internal Hex. is an internal connection endosseous subgingival implant system consisting of dental implants, prosthetic components and surgical instruments. Vulkan® Internal Hex. implants are made of titanium (grade 4) according to ISO 5832-2 with a surface topography obtained by VLA® surface treatment consisting of sandblasting and double acid etching.
The Vulkan® Internal Hex. implants are presented in a range of diameters 3.30, 3.75, 4.20 and 5.00 mm.

Intended use and indications

Vulkan® Internal Hex. implants are indicated for surgical placement in the maxilla and mandible of total or partial edentulous patients, in order to restore the patient's masticatory function. They are designed to support single or multi-unit restorations, also to retain overdentures. Vulkan® Internal Hex. dental implants can be used for immediate or delayed loading techniques. Immediate loading is only recommended when adequate primary stability is achieved.
Implants of diameter 3.30 are indicated only for the replacement of lateral unitary incisors in the maxilla and lateral or central unitary incisors in the mandible. Implants of diameter 3.30 should not be combined with angled transepithelial abutments and/or abutments with gingival heights greater than 3.0 mm.

Presentation of the Vulkan® Internal Hex. implant

Vulkan® Internal Hex. dental implants are subjected to a thorough manufacturing, control and cleaning process before being packaged in a sterile area and then further sterilized by gamma irradiation.
The implants are supplied in a sealed vial together with a cover screw attached to the vial cap. The implants are secured inside the vials by two titanium holders to avoid contact with any material than titanium and prevent possible contamination on their surfaces. The vial is then placed in a heat-sealed blister packaging to keep it sterilized until its expiry date.
Both, the external packaging (box) and blister packaging have a label which provides the following information: lot number, implant size and model and expiry date.
To ensure the compulsory traceability that dental implant is subjected to, please keep the label or transcribe its data to the patient's file.
Vulkan® Internal Hex. dental implants are supplied sterile and are intended for single-use be. Thus, under any circumstances contaminated implants should be cleaned and re-sterilized for reuse. Titanimplant S.L. will not accept any responsibility for re-sterilized implants, regardless of who had carried out the re-sterilization or which method had been used.

Contraindications

Vulkan® Internal Hex. dental implants should not be placed in patients discovered to be medically unfit for the intended treatment. The contraindications include the following: titanium allergy, metabolic or systemic disorders associated with wound and/or bone healing, bone previously irradiated, use of pharmaceuticals that inhibit or alter natural bone remodelling, uncontrolled diabetes, alcoholism or drug addiction, blood clotting disorders, anticoagulant therapy, diseases with periodic use of high doses of steroids, metabolic bone disease, chemotherapy or radiation therapy, chronic periodontal inflammation, insufficient soft tissue coverage, any disorders which inhibit a patient's ability to maintain adequate daily oral hygiene, uncontrolled parafunctional habits, moderate or severe smoking, uncontrollable endocrine diseases, insufficient height and/or width of bone, and insufficient interarch space, pregnancy, psychosis, vascular conditions.
Treatment of children is not recommended until growth is finished and epiphyseal closure has occurred.
It is recommended protection with bite splint in patients with parafunctional habits.

Side effects

It is the responsibility of the surgeon to provide the patient with all the information about side effects, precautions and possible complications that may arise following implant surgery as well as complete the informed consent form.

Warnings and precautions

Vulkan® Internal Hex. dental implants should be stored in their original protective packaging, in a cool dry place (room temperature) protected from direct exposure to sunlight.
Vulkan® Internal Hex. dental implants must not be reused in order to prevent contamination, especially from blood and saliva that can lead to cross-infection. Reuse of products that are labelled for single-use may also result in failure of the device to perform as intended due to change in its geometry. Any warranty claim resulting from the reuse of a single-use device will not be accepted.
Use of electrosurgery is contraindicated due to the conductivity of dental implants.
Vulkan® Internal Hex. dental implants have not been evaluated for safety, compatibility, heating or migration in the Magnetic Resonance Imaging environment.
Before surgery is the clinician's responsibility to check the state of the implant packaging and if it is the correct product to meet s the patient's needs.
Titanimplant S.L. advise to have always extra implants available.
When using our products during intraoral procedures mandatory precautions must be taken to prevent accidental aspiration/ingestion by the patient.
As part of the rehabilitation with dental implants and before the surgery it is the clinician's solely responsibility to carry out a thorough pre-operative assessment and planning of the whole treatment with the patient.
Precise planning should be done to avoid any accidental damage during the bed preparation and implant placement to vital anatomical structures, such as mental nerve and inferior alveolar nerve as this may result in anaesthesia, paraesthesia or dysaesthesia.

Surgical protocol

For a full surgical protocol, please visit our website: www.vulkanimplants.com/surgical-protocol

Disclaimer of warranty and liability

Vulkan® Internal Hex. implants are part of a broad concept and should be used only with original components and tools supplied by Titanimplant S.L.. The use of products manufactured by third parties, which are not supplied by Titanimplant S.L., will void any warranty or liability, express or implied, by Titanimplant S.L.

REF	Product number	STERILE R	Sterilized by radiation
LOT	Lot/Batch number		Use by (yyyy-mm)
	Consult instructions for use		Single use only
CE	CE marking		Do not resterilize
	Caution, read accompanying documents		Do not use if package is damaged
	Manufacturer	MD	Indicates the item is a medical device

CE 0051

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