INTERNAL HEXAGON IMPLANTS
Instructions for Use

Important: read carefully.

Disclaimer:
This product is part of a complete solution and can only be used with associated original products, in accordance with the instructions and recommendations of IDC® Implant & Dental Company. The non-recommended use of non-original products in combination with IDC® products will void any warranty and any other obligation, expressed or implied, by IDC®. The user of IDC® products has the duty to determine whether a product is suitable or not for the specific patient and the particular circumstances. IDC® disclaims any liability, expressed or implied, regarding direct, indirect, punitive or other damages deriving from or connected to any errors of assessment or professional practice made in the use of IDC® products. The user is also obliged to keep himself regularly updated on the latest developments relating to this product and its applications. In case of doubt, the user must contact IDC®. Since the use of the product takes place under the control of the user, the user assumes full responsibility for it. IDC® disclaims any responsibility for any resulting damage. Some products specified in these Instructions for Use may not have approval or authorization for sale in all markets.

Description:
Implants:
IDC® HELI® are endosse conical implants, with internal hexagon. The conical design provides greater initial stability than a parallel-walled implant. Its self-drilling properties together with an innovative spiral body allow you to change direction during insertion and to obtain high primary stability, even in very complex clinical situations.
The implants are made of commercially pure grade 5 biocompatible titanium with an SLA® surface. IDC® HELI® is available in three types:
HELI® with body completely treated with SLA®;
HELI® LUCID® with 1.00mm machined shiny collar and SLA® treated body;
HELI® FINE® with 1.00mm machined shiny collar and body treated with SLA® but with a less aggressive type of coils.
A cover screw made of Ti-6Al-4V titanium alloy is also included in the package.
It offers a wide range of fixtures to meet the most varied needs of implant-prosthetic rehabilitation.
Instruments:
All types of IDC® surgical drills: step drills, Step surgical drills, Step surgical drills (with Stop), cortical drills, Taps, ceramic drills and IDC® ball drills must be used in combination with IDC® implants.
All cutters are reusable and made of steel and must be replaced after 20-30 uses or when cutting efficiency decreases.
Intended use:
IDC® HELI® LUCID® FINE® CC® dental implants are indicated as anchoring or support of dental reconstructions in the upper jaw bone or in the jaw (osseointegration) to rehabilitate the masticatory function of patients.
Indications:
IDC® HELI® LUCID® FINE® CC® implants are indicated for applications ranging from the replacement of a single tooth to an entire fixed or removable arch, as well as overdenture elements capable of rehabilitating the chewing function of patients. To achieve this result, a 2-step or 1-step surgical technique can be used, in combination with immediate, early or delayed loading protocols, if sufficient primary stability and an appropriate occlusal load are recognized for the selected technique.

Contraindications:
IDC® HELI® LUCID® FINE® CC® implants are contraindicated for patients:
- clinically unsuitable for undergoing oral surgery procedures;
- with inadequate bone volume, where it is not possible to implement a bone grafting or regeneration procedure;
- for which it is not possible to reach the optimal size, number or position of the appropriate systems to obtain the safe support of functional or even parafunctional loads;
- allergic or hypersensitive to commercially pure titanium (Grade 5), to the titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), to steel or to the diamond carbon based coating (DLC).

Warnings:
An error in assessing the effective length of the drills compared to radiographic measurements can cause permanent injury to nerves or other vital structures. Milling beyond the depth foreseen by surgery on the jaw can cause a loss of sensitivity of the lower lip and of the chin region or hemorrhage of the oral floor.
In addition to the normal mandatory precautions for any surgery, such as asepsis, during milling in the maxillary bone, care must be taken not to damage nerves and blood vessels, referring to anatomical knowledge and preoperative radiographs.

Precautions:
General informations:
The success of an implant cannot be guaranteed 100%. Failure to comply with the limits of use and the procedures indicated can cause the system to fail.
Implant treatment can result in bone loss and biological damage or sagging, including failure of implants due to fatigue.
Close collaboration between surgeon, prosthetist and dental technician is essential for a successful implant treatment.
It is highly recommended that IDC® HELI® LUCID® FINE® CC® implants are used exclusively with IDC® surgical instruments and prosthetic components, as the combination with components not sized for the correct coupling can cause mechanical and / or instrumental problems, damage to the tissues or unsatisfactory aesthetic results.
It is highly recommended that the physician, even if experienced, always complete a special training program before using a new treatment method. IDC® offers a wide range of courses for different levels of knowledge and experience. For more information, visit www.idcimplant.com.
To avoid possible complications, the first time you use a new treatment method or a new device it is advisable to work alongside an expert colleague. For this purpose, IDC® provides a global network of consultants.

Before surgery:
It is essential to subject the patient to a careful clinical and radiological examination before surgery, in order to establish his physical and psychological conditions.
Particularly evaluate patients in whom systemic factors are present
or localized which could interfere with the healing process of the bone or soft tissues or with the osseointegration process (such as smoking, poor oral hygiene, uncontrolled diabetes, orofacial radiotherapy, steroid therapy, infections in the surrounding bone tissue).
Pay particular attention to patients undergoing bisphosphonate therapy. In general, the positioning of the implant and the prosthetic design must adapt to the patient's personal conditions. In the event of bruxism or an unfavorable intermaxillary relationship, it may be appropriate to consider a review of the treatment option.
Routine treatment of pediatric patients is not recommended until the conclusion of maxillary bone growth has been properly documented.
Preoperative deficits of soft or hard tissues can compromise the aesthetic result or determine an unfavorable angulation of the implant.

During surgery:
Be especially careful when placing narrow platform implants in the posterior regions due to the risk of prosthetic overload.
After implant installation, the surgeon's assessment of bone quality and initial stability will determine when to load the implants. The insufficient amount of bone tissue and / or the inadequate quality of the residual bone, as well as any infections and systemic diseases, can represent potential causes of osseointegration failure immediately after surgery or after an initial achievement of the same.
All instruments used in the surgical procedure must be kept in good condition. Take care that the instruments do not damage the implants or other components.
Due to the small size of the components, care must be taken to ensure that they are not swallowed or aspirated by the patient.
IDC® HELI® LUCID® FINE® CC® implants can be inclined up to 45 ° with respect to the occlusal plane. If used with angles between 30 ° and 45 °, observe the following indications: the inclined implant must be split; use at least 4 implants to support a fixed prosthesis on a totally edentulous arch.

After the surgery:
To ensure long-term results, it is advisable to regularly carry out patient follow-up sessions after implant treatment and to inform him about correct oral hygiene.

Materials:
IDC® HELI® LUCID® FINE® CC® Implant: commercially pure grade 4 titanium.
Cover screw: commercially pure grade 5 titanium.
Lancer drills, Step surgical drills, Step surgical drills (with Stop), Cortical drills, Taps:
Surgical Steel AISI Steel 3010

Cleaning and sterilization:
All IDC® HELI® LUCID® FINE® CC® implants are supplied sterile, are for single use and must be used by the indicated expiration date.

Warning: Do not use a device whose packaging is damaged or open.

Warning: all implants and drills are disposable and cannot be reused. The disinfection / sterilization process could cause a loss of mechanical, chemical and / or biological characteristics. Reuse could cause cross contamination.
All cutters are not supplied sterile and must be cleaned and sterilized before use.
For the United States: seal the device in a bag and steam sterilize it at 132 ° C (270 ° F) for 3 minutes.
Outside the United States: seal the device in a bag and steam sterilize it at 132 ° C – 135 ° C (270 ° F – 275 ° F) for 3 minutes.
UK alternative: seal the device in a bag and steam sterilize it at 134 ° C – 135 ° C (273 ° F – 275 ° F) for 3 minutes.

Warning: the use of non-sterile components can lead to tissue infection or the onset of infectious diseases.

A complete list of recommended parameters is provided in the "Cleaning & Sterilization Guidelines products IDC®" guidelines available on www.idcimplant.com or contact a IDC® representative to request the latest printed version.

MRI safety information:
Note that the safety and compatibility of the product in an MRI environment have not been evaluated. The product has not been tested for heating or migration in an MRI environment.

Conservation and management:
The product must be stored in a dry place in the original packaging at room temperature and must not be exposed to direct sunlight. Inadequate storage could affect the characteristics of the device causing it to rupture.

Disposal:
To dispose of the device, local regulations and environmental requirements must be followed, taking into account the different levels of contamination.

HELI IMPLANT SERIES
DiTRE CORTHO

Legend of the symbols used and company data

Read the warnings carefully
See instructions for use
REF Product code
STERILE R Sterile symbol
Non-reusable symbol
LOT Lot code
Use within
Do not use if the packaging is damaged
Do not release into the environment after use

CE 0425 **IDC® dental implants with the CE mark meet the requirements of the Medical Device Directive MDR EU 2017/745. 0425 is the number of the notified body.**

Manufacturer Anteea Srl
Viale Europa 126 O/P - 55012 loc. Lammari (Lu) Italy
Phone +39 0583 308371
www.anteea.com - info@anteea.com