INTERNAL HEXAGON IMPLANTS
CONICAL CONNECTION
Instructions for Use

Important: read carefully.

Limitation of Liability:

This product is part of a complete solution and may only be used with associated original products, in accordance with the instructions and recommendations of IDC® Implant & Dental Company. The non-advised use of non-genuine products in combination with IDC® products will void all warranties and any other obligations, express or implied, of IDC®. The user of IDC® products has the duty to determine whether or not a product is suitable for the specific patient and particular circumstances. IDC® disclaims any liability, express or implied, for direct, indirect, punitive or other damages arising out of or in connection with any errors of judgment 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. If in doubt, the user should contact IDC®. Since the use of the product takes place under the control of the user, he assumes full responsibility. IDC® disclaims any liability for any resulting damages. Some products specified in these Instructions for Use may not be approved or authorized for sale in all markets.

Description:

Implants:

IDC® HELI® are conical endosseous implants, with internal hexagon. The tapered design provides greater initial stability than a parallel-walled implant. Its self-drilling properties together with an innovative spiral body allow 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 fully treated with SLA®;
HELI® LUCID® with 1.00mm Machined Polished Collar and SLA® treated body;
HELI® FINE® with 1.00 mm machined polished collar and SLA® treated body but with a less aggressive coil type.
Also included in the package is a cover screw made of Ti-6Al-4V titanium alloy.
It offers a wide range of fixtures to satisfy the most varied needs of implant-prosthetic rehabilitation.

Instruments:

IDC® surgical drills of all types: 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 should be replaced after 20–30 uses or when cutting efficiency decreases.

Intended use:

IDC® HELI® LUCID® FINE® CC® dental implants are indicated as anchorage or support of dental reconstructions in the upper jaw bone or mandible (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 a fixed or removable entire arch, as well as elements for overdentures capable of rehabilitating the masticatory function of patients. To achieve this, a 2-stage or 1-stage surgical technique can be used, in combination with immediate, early, or delayed loading protocols, if sufficient primary stability and appropriate occlusal loading are recognized for the selected technique.

Contraindications:

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

Warnings:

Misjudging the actual length of the burs against radiographic measurements could result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended for jaw surgery may result in numbness of the lower lip and chin region or oral floor hemorrhage.
In addition to the normal precautions required for any surgery, such as asepsis, during drilling in the jaw bone care must be taken not to damage nerves and blood vessels by referring to knowledge of anatomy and preoperative radiographs.

Precautions:

General informations:

The success of an implant cannot be guaranteed 100%. Failure to comply with the indicated limits of use and procedures may result in implant failure.
Treatment with implants can lead to bone loss and biological damage or failure, including failure of implants from fatigue.
Close collaboration between the surgeon, prosthetist and dental technician is essential for the success of the implant treatment.
It is strongly 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 correct coupling can cause mechanical and/or instrumental problems, damage to the tissues or unsatisfactory aesthetic results.
It is strongly recommended that even experienced physicians always complete a special training program before using a new method of treatment. 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, it is best to work alongside an experienced colleague the first time you use a new treatment method or device. To this end, 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.
Particular attention should be paid to patients in whom systemic factors are present
or localized that could interfere with the bone or soft tissue healing process or with the osseointegration process (such as smoking, poor oral hygiene, uncontrolled diabetes, orofacial radiotherapy, steroid therapy, infections in the surrounding bone tissue).
Special care should be taken in patients receiving bisphosphonate therapy. In general, the placement of the implant and the prosthetic design must adapt to the personal conditions of the patient. In the event of bruxism or an unfavorable intermaxillary relationship, it may be appropriate to consider a re-examination of the treatment option.
Routine treatment of pediatric patients is not recommended until the conclusion of jaw bone growth has been properly documented.
Preoperative soft or hard tissue deficits can compromise the aesthetic result or determine an unfavorable angulation of the implant.

During surgery:

Particular care should be taken when placing narrow platform implants in the posterior regions due to the risk of prosthetic overload.
After implant installation, the surgeon's evaluation of bone quality and initial stability will determine when to load the implants. Insufficient amount of bone tissue and/or inadequate quality of residual bone, as well as possible infections and systemic diseases, can represent potential causes of failure of osseointegration 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 tools 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® Implants HELI® LUCID® FINE® CC® can be inclined up to 45° with respect to the occlusal plane. When used at angles between 30° and 45°, observe the following guidelines: the inclined implant must be splinted; use at least 4 implants to support a fixed prosthesis on a totally edentulous arch.

After surgery:

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

Materials:

HELI® LUCID® FINE® CC® IDC® Implant: Grade 4 commercially pure titanium.
Cover Screw: Grade 5 commercially pure titanium.
Launched drills, Step surgical drills, Step surgical drills (with Stop), Cortical drills, Taps:
AISI Steel 3010 surgical steel

Cleaning and sterilization:

All HELI® LUCID® FINE® CC® IDC® Implants are supplied sterile, are intended for single use only and must be used by the stated expiration date.

Warning: Do not use a device whose package is damaged or opened.

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

Warning: The use of non-sterile components may lead to tissue infection or infectious disease.

A complete list of recommended parameters is provided in the "Cleaning and Sterilization" guidelines. IDC® Product Guidelines" available at www.idcimplant.com or contact an IDC® representative to request the latest printed version.

MRI Safety Information:

Please note that the safety and compatibility of the product in an MR environment have not been evaluated. The product has not been tested for heating or migration in an MR environment.

Conservation and management:

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

Disposal:

When disposing of the device, local regulations and environmental requirements must be followed, taking into consideration the different levels of contamination.

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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.**

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