## Instruction for use
## System of Dental Plates CF@O, Cortically Fixed at Once

### Description

The Dental Plate Implant is intended for the surgical placement in the mouth to support bridges or overdentures in the edentulous or partially edentulous patient for the rehabilitation of the atrophic jaw in order to restore the chewing function.

The Dental Plate is a single-component implant and is made from Unalloyed Commercially Pure (CP) Titanium. HA/TCP is used as a sandblasting media with later etching for surface cleaning and reaching the surface microtopography on the side of the implant which is intended to be connected with the bone.

The abutment is designed for a screw retained type of fixation.

The Dental Plate is delivered in a sterile package with a multifunctional carrier. Secondary box has peel-off stickers for the clinical documentation and the implant passport

### Intended Purpose

HENGG1: To be used in the atrophic maxilla (where bone height is minimum 1mm). Fixation beneath the sinus maxillary, with bone screws in the cortical bone at the zygomatic arch and at the palate. Cannot be used to replace a single missing tooth

HENGG-2: To be used in the atrophic maxilla in the premaxillary region (where there is no bone width and no bone height) and in the atrophic mandible (pencil mandible) where there is no bone width in the retromolar region.Cannot be used to replace a single missing tooth

HENGG-3: To be used in the atrophic mandible (where the bone height is minimum 5 mm). The fixation is in the retromolar region of the mandible-.Cannot be used to replace a single missing tooth.

HENGG-4: To be used in the atrophic maxilla, premaxilla (where bone height is 1 mm) in combination with HENGG-1. Fixation in the premaxillary region.Cannot be used to replace a single missing tooth

Bone screws: Bone screws used to fixate the plate to the bone

### Intended use

The Dental Plate Implant is intended for the surgical placement in the mouth to support bridges or overdentures in the edentulous or partially edentulous patient for the rehabilitation of the atrophic jaw in order to restore the chewing function

### Intended Users

Plates implantation must be performed by Oral and Maxillofacial Surgeons and Periodontists with knowledge of dental implantology. Practitioners must have the knowledge of instruction for use of Dental Plates.

### Indications

The Dental Plates are used in cases when the residual bone is only between 0 mm and 5 mm in the atrophic bone and when bone graft or sinus lift are contraindicated and as a treatment option . The sites of usage are the retromandibular trigone area in the mandible, the zygomatic and canine region in the maxilla. These implants are placed at immediate loading or delayed loading and are just used in conjunction with other dental implants in the same prosthetic implant reconstruction scope. They never can be used to replace a single missing tooth.

The bone screws to the Dental Plates are used for the fixation of the Plate Implants on the cortical bone.

These Plates are used as sustenance to the Cortically Fixed implants, two piece and One Piece Implants

### Contraindications

The contraindication to place implants will be evaluated by the professionals on a case-by-case basis, with the greatest caution. Preoperative diagnosis is necessary to identify threats to the patient, related to the procedure of the implant placement, as well as factors that may affect the possibility of healing of the bone and surrounding soft tissues.

Dental Plates cannot be used alone, but always in combination with other dental implants.

They allow a vertical stabilization of the suprastructures, and are essential in the total rehabilitation of the atrophic maxilla and/or mandible and above all they allow an immediate loading or a delayed loading without bone graft, sinus-lift, nore nerve displacement.

As a contraindication determined usage of the Plate is to use it as a single implant.

Patients whose overall systemic condition does not permit implantation, inadequate bone material (less than 1mm), before, during and after irradiation therapy or in the presence of malignant processes, psychological disorders, pain syndromes, uncompensated diabetes or other uncompensated systemic processes, inadequate oral hygiene, inadequate, allergies to implant material, diabetes, bruxism, allergies, pregnancy, alcohol and drug abuse, smoking, inadequate bone supply, especially in the vertical dimension, or in the immediate vicinity of endangered structures (nerves, maxillary sinus etc).

**Side effects, complications with DENTAL PLATE- implants**

Immediately after the insertion of Dental Plates, activities that demand considerable physical effort should be avoided. Possible complications following the insertion of the Dental Plates are:

Temporary symptoms: pain, swelling, phonetic difficulty and gingival inflammation.

More persistent symptoms: chronic pain in connection with implants, permanent paraesthesia, dysesthesia, loss of maxillary / mandibular ridge bone, localized infection, oroantral or oronasal fistula, unfavourably affected adjacent teeth, fracture of a plate, jaw, bone or prosthesis, aesthetic problems, nerve damage, exfoliation, hyperplasia

**Warning**

Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury. Beside the mandatory precautions for any surgery such as asepsis, during drilling in the jaw bone, one must avoid to damage the nerves and vessels by referring to the anatomical knowledge and preoperative medical imaging (e.g. radiographs)

Failure to recognize the actual length of the drills relative to the radiographic measurements can result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to hemorrhage in the floor of the mouth.

Do not use devices if the primary package has been damaged or previously opened.

Do not use damaged or blunt instruments for implantation.

The plastic implant holder is not intended to be used as an insertion tool. It is prohibited to apply torque to the plastic implant holder to screw in the implant. Only the designated instruments may be used for implant insertion.

**Warnings / Precautions**

**General:**

Bone screws available in the market can be used with the Dental Plates, Practitioner should ensure the bone screws are sterile. Should any screws be delivered with plates, they must be sterilized prior to use.

Sterile handling is essential. Never use potentially contaminated components. Contamination may lead to infection.

Do not resterilize Dental Plates.

Avoid any contact of the Plate with foreign substances prior to their use. Do not touch the Plate side which is sandblasted.

The Dental Plate should be used according to its expiration date.

If the Dental Plate is not assembled any more with its holder and just moving into the blister, DO NOT USE this Plate because the surface is already contaminated by plastic particles.

One hundred percent success rate cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may result in failure.

Treatment by means of Dental Plates may lead to the loss of bone, biologic and mechanical failures, including fatigue fracture.

Close cooperation between the surgeon, the restorative dentist and the dental laboratory technician is essential for a successful implant treatment.

It is recommended that Dental Plates are used only with dedicated surgical instruments and prosthetic components. As violation of this recommendation may lead to mechanical instrumental failure or unsatisfactory treatment result.

It is strongly recommended that clinicians, new as well as experienced users, always go through a special training before using a new product or treatment technique.

All Dental Plates are delivered in a sterile package with carrier. The carrier is only for handling the Plate and screws over and first placement into the cavity.

Magnetic Resonance Imaging (MRI). Safety information: these products are fabricated from a metal material which can be affected by MRI energy.

**Before surgery:**

Clinical and radiological examination of the patient has to be performed prior to the surgery to determine the psychological and the physical status of the patient.

Special attention has to be given to patients who have localized or systemic factors that could interfere with the healing process of the bone, or the soft tissue, or the osseointegration process (e.g. smoking, poor oral hygiene, uncontrolled diabetes, facial radiotherapy, infections in neighbourhood tooth or bone, patients passed bisphosphonate therapy).

Preoperative hard tissue and soft tissue deficit may yield to compromised aesthetic result.

**At surgery:**

All instruments and toolings used during the procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

After the implant installation, the surgeon's evaluation of bone quality and primary stability will determine when implants may be loaded.

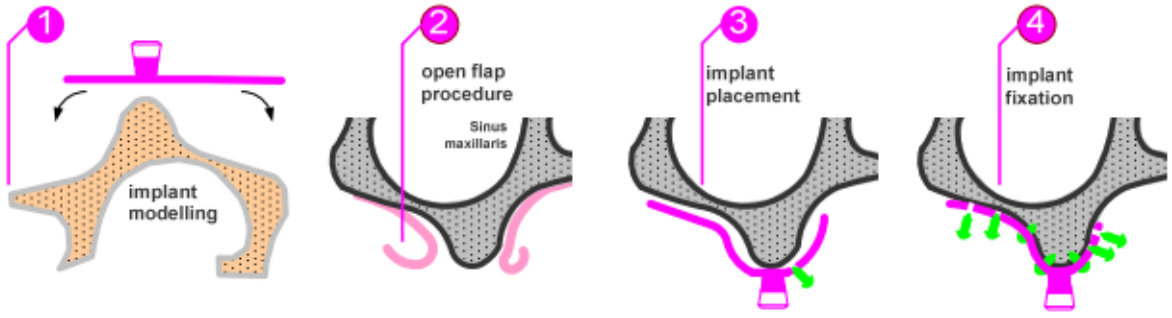
**After the surgery:**

To secure the long term treatment outcome it is recommended to provide comprehensive regular patients follow up after the implant treatment and inform about necessary of appropriate oral hygiene.

**Processing**

For the ease of use, the implants show the same head-part as the BI-X2 implant. A centering eyecup on the base of the implant, which allows the stabilization of the implant before placing the other screws, makes insertion very safe.

1. produce a 3D-model of patients situation form the implant anatomically on the 3D model before surgery clean, sterilize and pack the implant according to instruction for sterilization
2. open flap procedure determination of anchor points
3. place the implant on the bone and fix it with surgical screw on centering eyecup. Place surgical screws in the eyelets going from the center to the edge.




As a result, at given indication prosthetics can be immediately fitted on the implant. Within a few days time the final secondary structure shall be screwed. An immediate prosthetic splinting through a temporary bridge is recommended.

**Impression and laboratory**

1. Screw the transfer post on the inserted implant.
2. Take an impression of the implanted situation with an individual tray.
3. Unscrew the transfer post and screw on the lab-analog
4. Transfer model to the laboratory to proceed with the denture

**Storage**

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

Do not reuse Dental Plates and bone screws to them. Do not use Dental Plates and bone screws after expiry date indicated on the packaging.

**Disposal**

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

**Materials**

Dental Plates: Commercially pure titanium (Ti Gr2)

Bone Screws: Titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).

Drills, insertions tools, screwdrivers, ratchets: stainless steel

Handless, screw removals, compressive screws: titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).

**Compatibility information**

For all Dental Plates one-platform has been especially developed. No matter which size of plate and implants are used, it will have the same platform. (Exception Root Form) It is helpful to eliminate stock and simplify the practice.

**Cleaning and disinfection**

Dental Plates and bone screws are delivered sterile and for single use only prior to the labeled expiration date. They must not be cleaned and sterilized.

**Sterilization**

Dental Plates and bone screws are delivered sterile. The intact sterile packaging protects the sterilized implant from external influences and if stored correctly, the packaging ensures sterility up to the expiration date. The sterile packaging must not be opened until immediately prior to the insertion of the implant. When removing the Dental Plate and bone screws from the sterile packaging, rules of asepsis must be observed. The sterile packaging must not be opened until immediately prior to the insertion of the implant.

**Preoperative planning**

The Dental Plates and the bone screws, their type, position and number of implants should be selected individually taking the anatomy and spatial circumstances into account. Before implant treatments various tests should be done:

Blood test, Mouth examination, X-ray examination, CT examination.

**Implant bed preparation**

Under local anaesthesia for the placement of the Plate drills are used. For the preparation of the appropriate place for the Dental Plate it is recommended to use drills and observe the technology of preparation of the bone bed. Regarding the rotations per minute, intermittent drilling techniques and adequate cooling, the IFU of the drilling procedure should be reviewed prior to attempting placement.

**Plate Placement**

The Plate is removed from the sterile packaging immediately prior to the introduction, bended and must be stably installed in the implant bed prepared. Be sure to install it securely immediately and perfectly adapted to the bone. The Dental Plate is fixed with screws, after the perfect adaptation to the bone.

**Wound treatment**

The Dental Plate may be used in combination with immediate loading or delayed loading.

**Healing phase**

The Dental Plates are used for multiple unit restorations with immediate loading or delayed loading in the upper and lower jaws with adequate bone tissue.

**After treatment:**

- After implantation the patient record must include the types of the used implants and lot number (put inside on a card with a special label which is located in the box with the implant)
- Products must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use devices in accordance with these instructions and determine if the device fits to the individual patient situation.

**Validity**

Upon publication of these instructions for use (IFU), all previous versions are superseded.

**Please note**

For the purpose of legibility, does not use ™ or ® in the text. This does not affect rights with regards to registered trademarks.

Some products may not be available in all markets. Please contact your local representative to review the product range available.

**Signs explanation**

| | |
|---|---|
|  | Consult instructions for use |
|  | Catalogue number |
|  | Batch code |
|  | Use by |
|  | Sterilized using irradiation |
|  | Do not use if package is damaged |
|  | Do not reuse |
|  | Keep away from sunlight |
|  | Keep away from water |
|  | Manufacturer |