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OT-F²
Surgical Manual

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Introduction

The OT-F² implants are self-tapping cylindrical screw implants made of titanium grade 4 for insertion down to the bone crest level. The surgical protocol is usually twophase, but can be one-phase in special cases at corresponding indication.

The implants are available in multiple sizes (diameters 3.40/3.80/4.10/5.00 mm and lengths of 8/10/12/14/16 mm), providing a wide indication spectrum if there is sufficient vertical as well as horizontal bone quantity. The indication range is increased by surgical procedures such as augmentation, bone spreading or bone splitting.

The OT-F² implant is suitable not only for insertion in completely healed jaw bone (late implantation), but also for delayed insertion (6-8 weeks after tooth extraction), as well as at corresponding preconditions for immediate implantation (directly after tooth extraction).

The implant diameter should be selected accordingly to fill out the extraction site diameter completely or ideally to slightly expand the site, considering the planned prosthetic type of restoration.

The choice of correct implant size is not only determined by the anatomic situation of mandible and maxilla, but especially dependent on the desired type of prosthetic restoration, in order to avoid possible overloading.

Important:
Please follow the general and special contraindications contained in the Instructions for Use and in addition the indication restrictions for implants with a diameter of 3.40 mm!

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The Packaging

The color coding system

The OT-F² implants are provided in different diameters and lengths in order to cover multiple indications. The color coding of all components facilitates their allocation. These color codes are contained on all implant and prosthetic packings.
All Surgical Drills, Implant Drivers, Cover Screws, Healing Abutments and Impression Copings as well as all abutments are color coded according to all diameters.

The outer package and the labels provide valuable information about the enclosed product before opening: Sterilization expiry date, implant length and diameter, article and lot number.
The lot number is the basis for traceability of relevant product information and is essential in the preparation of potential returns or warranty claims.

The packaging contains the Instructions for Use with important instructions as to how the implant should be inserted. In addition, the adhesive stickers are contained which can be used in the documentation of patient records or with the implant passport.

Diameter	Color code	Color markings
3.40 mm	green	
3.80 mm	yellow	
4.10 mm	red	
5.00 mm	blue	

The Packaging

The implant is supplied in a gamma sterilized package which includes the appropriate Cover Screw. Both parts are maintained in a sterile atmosphere until use, even after opening of the blister. This is possible due to the sliding chamber made of a shock-proof resistant acrylic material which is provided with a color coded platelet of acrylic (according to the color coding system). This chamber contains the Implant as well as the Cover Screw.

The OT-F² implant is mounted on an Implant Driver with latch shaft within the package. Basically, the doctor can decide for applying either the mechanical or the manual insertion technique. Open the chamber by pulling off the transparent long cap from the black implant carrier.

Please take additional information from the enclosed Instructions for Use.

For mechanical insertion, the latch shaft of the Implant Driver is directly fixed within the contra-angle (Fig. 1), while for manual insertion the Finger Key is assembled first with the Adapter and then fixed with the latch shaft of the Implant Driver within the Adapter (Fig. 2).

For insertion, the implant is removed from the black carrier and can then be fixed within the bone preparation (by manual or mechanical method).

Fig. 1

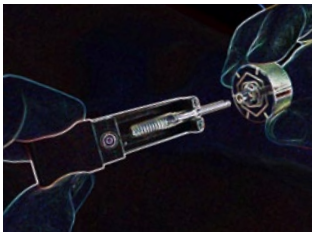

Fig. 2

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Preparation

Any implantation should in principle be preceded by a thorough clinical examination. For an exact diagnosis, the use of a panoramic radiograph and a template prepared in the laboratory is mandatory. The X-ray indicator helps to determine the optimal length and the diameter of the implant for the insertion site prior to surgery. The X-ray indicator which corresponds with the magnification factor of the X-ray unit used, is placed on the radiograph.

A sufficient number of implants in different lengths and diameters should be available during surgery as in many cases the definitive decision as to which implant would have the optimal dimensions for the revealed bone anatomy can be made only after exposure of the jaw bone.

An additional aid for diagnosis is the threedimensional CT or DVT scan method in order to decide for the exact implantation planning and surgery.

In many cases, model or computer supported surgery templates based on a virtual surgery planning at the computer, can be recommended. This guarantees a high safety both for the doctor and the patient.
An intra-operative decision for the suitable implant size as described above, is usually not necessary with this method.

Note:
The special implant and prosthetic modalities of a treatment according to the „Multi Unit" concept with components of the 4plus6Line are not described in detail in this surgical manual, as special knowledge and experience by the responsible team are required.

Surgical Tray

The Surgical Tray is compact and well-accessible and contains all drills and accessories for insertion of the OT-F² implants of 3.40 mm to 5.00 mm diameter.

Immediately after insertion, the implants should be protected with the Cover Screw contained in the implant package.
For the gingival healing phase, Healing Abutments in standard straight and additional standard flared and slim flared shape are available.

For impression taking, the doctor can choose between Impression Copings for the closed or the open impression.
The ideal planning prior to surgery should encompass the awareness about the available prosthetic abutments and their indications which the implant system offers.

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Prosthetics

Prosthetic Abutments

The prosthetic variations of the OT-F² implant system features versatility, but also a simplicity at the same time. The system offers constructions from single tooth replacement to small and also large bridges up to an edentulous jaw reconstruction in different variations. If cemented, screw-fixed or removable by the dentist, the denture may be standard, individually custom-made or highly esthetic, everything is possible.

The following prosthetic abutments are available:

- **Temporary Abutment „CreativeLine" (titanium)**
  For temporary restoration and design of the emergence profile
- **Anatomical titanium abutment „NaturalLine"**
  For the restoration of cemented crowns and bridges
- **Massive abutment titanium „VersaLine"**
  For the preparation of individual abutments by trimming from the complete piece, especially for the telescope and conical crown technique
- **Gold base abutment „GoldLine"** (cast-on)
  Abutment for cast-on for preparation of individual abutments in precious metal alloys.
- **CAD/CAM abutment „HighLine"**
  High quality abutment with titanium base for preparation of individual zirconium abutments by CAD/CAM or also copy drilling procedure
- **Zirconium abutment „CeraLine"**
  High quality zirconium standard abutment with titanium base for the preparation of individual zirconium abutments.
- **Bar abutment system „ProfiLine"** (one or two part)
  Non-antirotation abutment made of titanium or of precious metal for compensation of divergencies for the preparation of customized and individual bar constructions. An Adapter for compensation of the gingiva height is available in addition.
- **Preforms**
  Massive titanium abutment for individual milled titanium abutments by CAD/CAM methods.
- **Multi Unit Abutment „4plus6Line"**
  For restoration of edentulous jaws with dentist-removable bridges. The abutments of 0°/17°/30° are supplied in **sterile** condition for direct intra-surgical use.
- **Ball head abutment „TecLine"**
  For anchorage of complete prostheses with O-ring or Dalbo® Plus elliptic attachments
- **LOCATOR® Abutment**
  For anchorage of complete prostheses with original LOCATOR® retention elements (Zest Anchors, USA)
- **Magnet Abutment „Titanmagnetics®"**
  For anchorage of complete prostheses with original counter-magnets (Distributor steco, Hamburg; Germany)

IMPORTANT NOTE
Abutments with abutment screws are supplied with the Laboratory Screw mounted. The color coded Final Screw is contained within the square cover plug of the acrylic vial in the prosthetic package and is used for final fixation of the abutment in the mouth of the patient applying 35 Ncm (except for CreativeLine with 15 Ncm).
An exception are the 4plus6Line abutments which are supplied with the corresponding Final Screw mounted, for immediate intra-surgical use.

Please see detailed information in the product catalog.

* Hersteller: Cendres & Métaux; Schweiz

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Preparation

See now: Surgical video of OT-F² insertion

Step-by-Step Instructions for the Bone Preparation

All drills are cooled externally and have no internal cooling (which would be very difficult to clean). The drills are inserted into the jaw bone with careful up and down movements. Any bone particles should be carefully preserved and used later for a possibly necessary augmentation.
Important: The drills must not be used more than 15 times as otherwise optimum cutting action cannot be guaranteed.

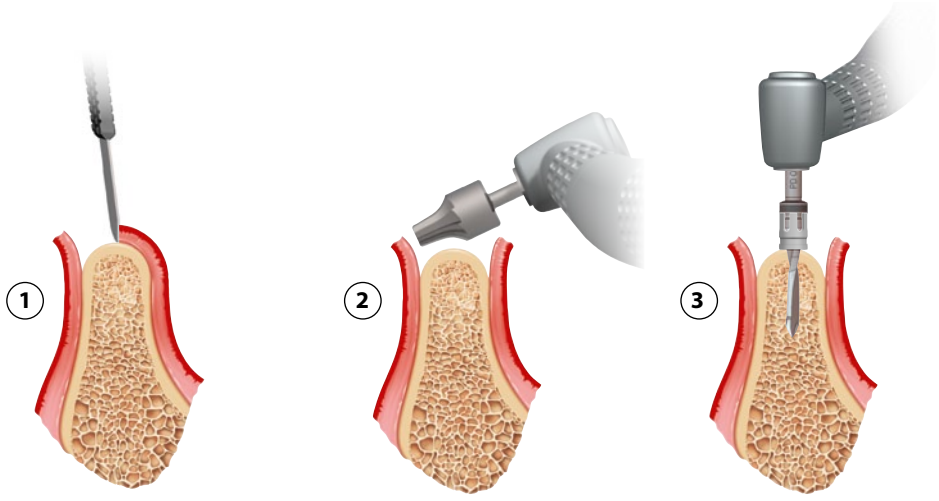
Step 1: Exposure
OT-F² implants are inserted after exposure of the jaw bone. The doctor decides on individual incisions in the present situation.

Step 2: Preparation of the alveolar bone
Unfavorable protrusions of the alveolar crest such as small or even sharp edges can be removed by using the Bone Trephine in order to create a corresponding level for insertion of the implant.

Step 3: Perforation of the cortical plate / pilot preparation
The cortical bone plate is perforated in exact vertical direction parallel to the axis by using the Pilot Drill (Ø2.0 mm). This is a very sharp double-sided cutting drill which facilitates the first drill preparation considerably, as opposed to a conventional rose head bur (recommended torque 1,100 rpm). The Pilot Drill has at the depth marking a diameter of 2.6 mm in order to make the insertion of the following Final Drill easier. This drill can be used with a Drill Stop (grey) for safety.

Note

The drills can be used with or without a Drill Stop. The Surgical Tray contains, in addition to the Pilot Drills in specific lengths, exactly congruent drills for each implant diameter (3.40/3.80/4.10/5.00 mm) and each implant length (8/10/12/14/16 mm). The length indication on the shaft corresponds with the laser marking.



Preparation

Step 4: Control check No. 1
The Depth Gauge (Ø2.0 mm) can now be inserted for an exact control of the prepared depth. The laser markings (8/10/12/14/16 mm) correspond with the Pilot and following Drills.

Step 5: Control check No. 2
In order to keep a parallel adjustment of the implants at unguided implant bone preparation, the use of a Direction Indicator is now required. This instrument should be placed into the preparation with the thin (Ø2.0 mm) part of the shaft and indicates the direction of the axis for adjustment of the additional bone preparations.

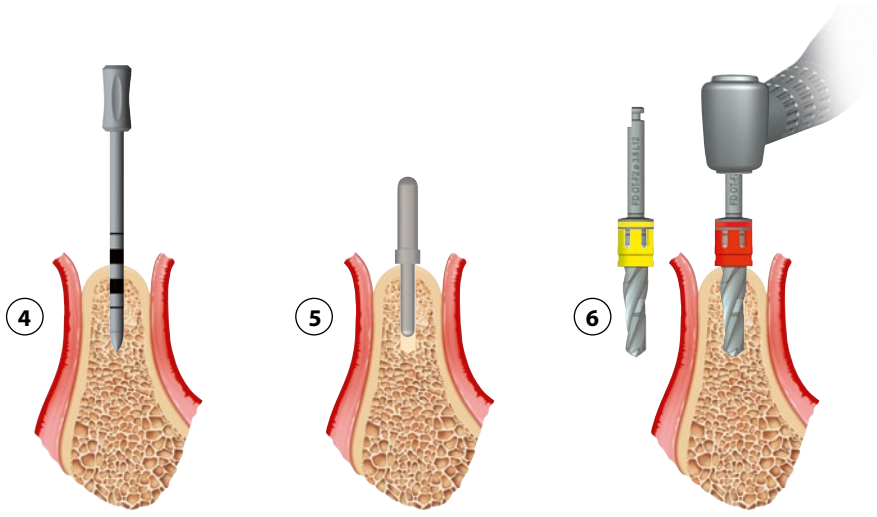
Step 6: Expansion of the preparation
The expansion of the implant site preparation is made successively with the color coded Final Drills to the final implant diameter. The drills are slightly underdimensioned and have laser markings for the drill depth.
Please follow the markings in the Surgical Tray for the drill sequence. According to the final implant diameter to be used, the next larger Final Drill will be used step by step:

- **Final Drill 3.40** – green marking (recommended speed: 1.000 rpm)
- **Final Drill 3.80** – yellow marking (recommended speed: 900 rpm)
- **Final Drill 4.10** – red marking (recommended speed: 900 rpm)
- **Final Drill 5.00** – blue marking (recommended speed: 800 rpm)

Please note the graphic illustration „Sequence of drills (Drill Protocol) for insertion of OT-F² implants“ on page 8. This demonstrates an example for the sequence of drills to be used for insertion of an implant of 4.1 mm diameter and 12 mm length.

The „Multi Unit“ treatment concept
The Multi Unit concept (4plus6Line) serves for rehabilitation of edentulous jaws and can avoid extensive augmentation methods. The insertion of four (in the maxilla six) implants is sufficient whereby the posterior implants of preferably 14 or 16 mm length are inserted with an angulation of approx. 30° to the distal. We recommend to use a drilling guide template for the pilot preparations. Please note that Drill Stops must not be used for the „Multi Unit“ concept when the angulation is very strong.
After insertion of the implant, the abutment should be inserted easily and should not collide with the distal bone edge. If this is assured, the abutment can be fixed by applying 35 Ncm.

Aim of this treatment method is the immediate restoration (immediate loading) of the implants with a screw-connected temporary bridge within only one visit.



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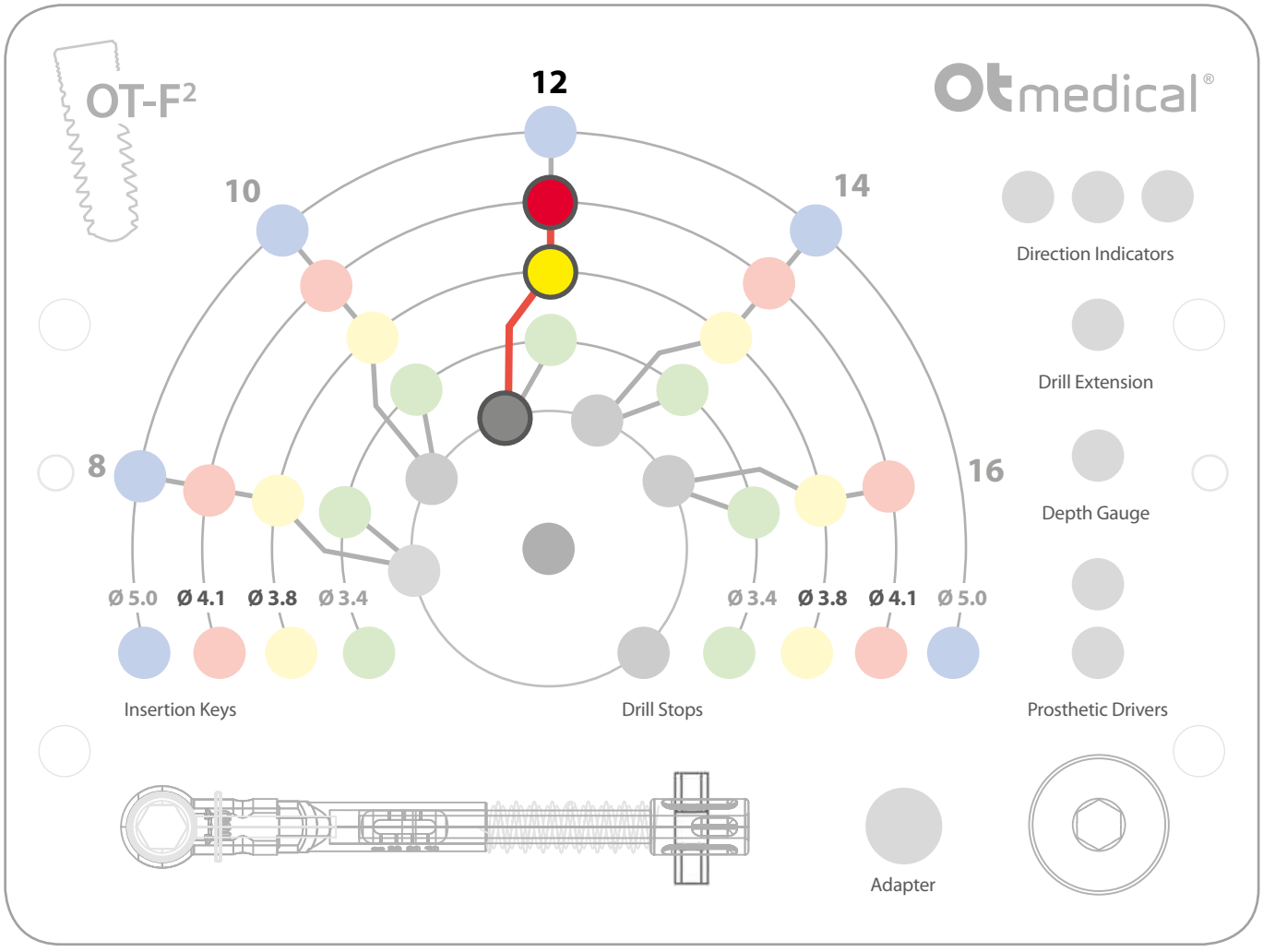
Drill protocol for bone preparation

The graphic illustration demonstrates an example for the sequence of drills to be used for insertion of an OT-F² implant of 4.1 mm diameter and 12 mm length.



Insertion

Step by step instructions for the implant insertion

The OT-F² implant is mounted in the package on an Implant Driver with a latch shaft. Basically we can choose between mechanical or manual insertion.

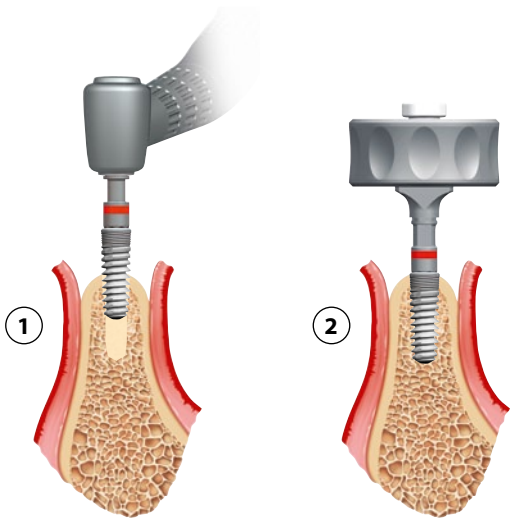
Retrieval of the implant
For mechanical insertion, the latch shaft of the Implant Driver is directly fixed in the contra-angle hand piece and the implant retrieved from the mount. For manual insertion, the Finger Key is placed onto the Adapter. The Adapter serves as a fixation for the latch shaft for the Implant Driver and thus enables manual insertion.
Please make sure, after removal of the implant from the sterile acrylic slide chamber, that the implant does not come in contact with for instance saliva, neighboring teeth, instruments or saline solution, to avoid contamination.

Step 1: Insertion
Place the implant directly into the bone preparation which has filled with blood. Take special care not to contaminate with saliva, saline solution or other material. With a complete turn of 360° the implant will be inserted by approx. 1.1 mm depth. The self-cutting compression threads of the OT-F² implant increase the friction by proceeding into depth of the prepared site.

Mechanical insertion:
For the mechanical insertion of OT-F² implants we recommend to set the surgical unit at a revolution speed of 15 rpm. If the transport pin is removed from the implant inner contour before complete insertion please change to the color coded Implant Driver with latch for contra-angle out of the Surgical Tray. In order to avoid possible necroses of the surrounding bone by pressure, do not exceed the insertion speed of max. 50 Ncm.

Manual insertion:
If you feel the screw-in resistance is too high, turn the implant slightly back counter-clockwise (120 –180°) and then again start with clockwise rotation. Repeat this procedure until the implant has reached the final depth and is level with the crest of the jawbone as ideal situation. Do not exceed the screw-in resistance of max. 50 Ncm. If the space situation in the mouth of the patient is unfavorable, use the Drill Extension.

Do not use the Torque Wrench for manual insertion, but use this only during the final phase of the insertion. In order to guarantee an optimal prosthetic restoration, try to obtain the most favorable position of the internal FourByFour® connection when finally positioning the implant.



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Insertion

Step by step instructions for the implant insertion

Step 2: Implant coverage
The internal contours of the implant must be thoroughly cleaned with saline solution prior to covering of the implant. For submerged healing the Cover Screw of corresponding diameter contained in the implant package is placed on the implant. Use the friction-grip Prosthetic Driver 1.30 Hex for removing the Cover Screw from the mount and cover the implant which has just been inserted.

The Cover Screw should be tightened carefully (torque < 10 Ncm). When an open transgingival healing is planned, please choose a corresponding Healing Abutment (sterilized prior to use) and place onto the implant instead of the Cover Screw by using the Prosthetic Driver.

For a restoration with the „Multi Unit" treatment concept, the pertaining (sterile packed) 4plus6Line abutments are placed at this point, appropriately adjusted for prosthetics and fixed by applying 35 Ncm. [The particular implant and restorative procedures in this treatment concept is restricted to the experienced and specially trained users.]

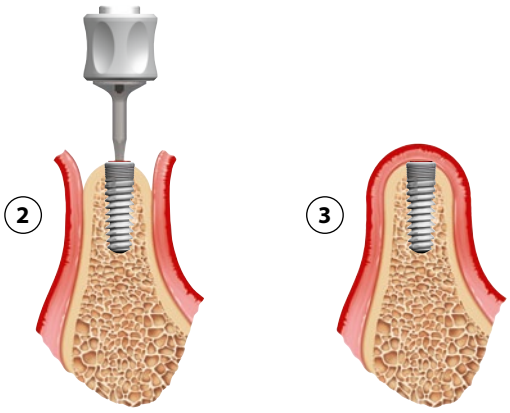
Step 3: Wound coverage/suturing
When closing the mucous membrane, make sure that the sutures are placed without tension. The type of suture technique is up to the doctor's decision.

Healing time
The length of the healing time depends on several factors:
- bone quality D1-D4 (mandible/maxilla)
- implant surface (NanoPlast® Plus)
- time of insertion (immediate/delayed/late)
- age and state of health of the patient
- required augmentation procedures

etc.

Principal rule for healing time of OT-F² implants:
3 months in the mandible, 6 months in the maxilla

A prolonged healing time due to the smaller implant surface of implants with a diameter of 3.40 mm should be accounted for. For control of the healing process a perio-test check is recommended. At transgingival healing, the implants should be allowed to osseointegrate without loading. Please take care that the Healing Abutments should be selected – considering the planned later prosthetic restoration – with a height which will protrude from the gingiva, but on the other hand do not transfer any loading forces on the implant. Special attention should be focused on the fact that there should be absolutely no contact to the antagonists.



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Exposure and Impression

Exposure of the implants

When the healing time has elapsed, the mucous membrane is reentered in order to expose the implants (Fig. 1).
The doctor decides which type of incision he will use, which Healing Abutment should be inserted and which suture technique would be favorable in each case.

Exposure by laser technology is also indicated and is up to the surgeon's decision as well. The exposure can also be indicated in certain cases by using a manual centering punch.
The insertion of Healing Abutments according to the implant diameter, the thickness of the mucous membrane and the planned prosthesis is indicated. The Healing Abutment should be tightened carefully (torque < 10 Ncm) (Fig. 2).

At this point we recommend:
• check-up by a perio-test in order to control the osseointegration
• panoramic radiograph for documentation

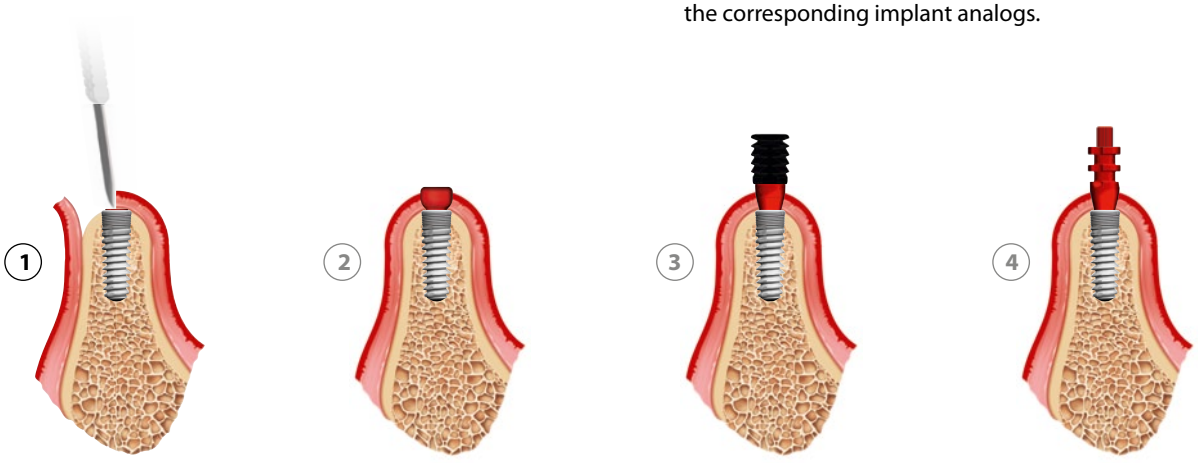
If an immediate temporary primary restoration with the abutments „CreativeLine" is planned with temporary crowns, we recommend to prepare these in anatomically smaller shape and to anchor these in stable connection to the neighboring teeth.

Impression taking

After complete healing of the gingiva, the impression can be taken. The implant system offers a selection between closed (reposition technique) (Fig. 3) and open impression method (pick-up technique) (Fig 4).
Remove the Healing Abutments, place the Impression Copings onto the implants and fix with the corresponding fixation screws. The FourByFour® connection provides an exact transfer of the implant position to the master model to be prepared. When ordering the Impression Coping „Closed Tray" acrylic Transfer Copings are included and must be used for the clear and precise placement in the impression material. We recommend using an individually prepared impression tray for the impression taking.

Closed impression:
After curing of the impression material, the individually prepared impression tray is removed from the mouth of the patient. The Impression Copings are removed from the implants and screwed onto the corresponding implant analogs and then repositioned into the Transfer Copings which have remained in the impression. The Transfer Copings are for one-way use only.

Open impression:
After curing of the impression material, the screws of the Impression Copings are removed through the perforations in the impression tray. The individual impression tray is removed from the mouth. The Impression Copings have disconnected from the implants and are fixed stable within the impression. The screws of the Impression Copings are repositioned to allow screwing in the corresponding implant analogs.



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