E

otmedical®

Innovative Präzision
Made in Germany

OT-F³
Surgical Manual

Introduction

The OT-F³ implant is a two-phase implant with cone-shaped design and slightly round apical diameter for insertion by tapping down to the bone level. The surface shows a three dimensional structure consisting of ball-shaped particles applied by a sintering process.

The implants are available in diameters 3.80/4.10/5.00 mm and lengths of 5/7/9 mm, assuring a special indication spectrum at sufficient horizontal bone. This allows an insertion of OT-F³ implants in severely atrophied jaws up to a minimum height of only 5 mm and a minimum width – at least 1.8 mm buccal bone lamella –in the maxilla as well as in the mandibular jaw.

The OT-F³ implant is suitable for insertion in completely healed jaw bone (late implantation). OT-F³ implants should not be inserted in severely cortical bone (D1) because of the reduced blood support.

Surgical procedures such as augmentation, bone spreading or bone splitting or bone grafts in direct contact to the OT-F³ implant should not take place simultaneously with the implantation, but should be completely healed at this point. However, there is an indication to place an internal sinus lift at the same time with the osteotome technique. This allows in such cases the possibility to insert a 5.0 mm short OT-F³ implant in only 3 mm flat bone.

Note:
For all other indications not mentioned above, the OT-F² implant system is ideally suitable (see page 15).
OT-F³ and OT-F² both have a FourByFour® internal connection which favors a uniform prosthetics concept.

The selection of the suitable implant size is not only indicated by the anatomical situation of the maxillary or mandibular jaw, but also depending on the planned prosthetic reconstruction in order to avoid any possible overloading.

All OT-F³ components are made of titanium grade 5 (Ti6Al4V). Please take detailed information on material and the implant surface as well as safety techniques from the OT-F²/OT-F³ product catalog or the material data sheet.

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The Packaging

The color coding system

In order to cover multiple indications, the OT-F³ implant system contains several diameters and lengths. The color coding of all components facilitates their allocation. These color codes are contained on all implant and prosthetic packings.
All surgical drills, trial fit gauges, osteotome tips, implant drivers, cover screws, healing abutments, impression copings and 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
3.80 mm	yellow	
4.10 mm	red	
5.00 mm	blue	

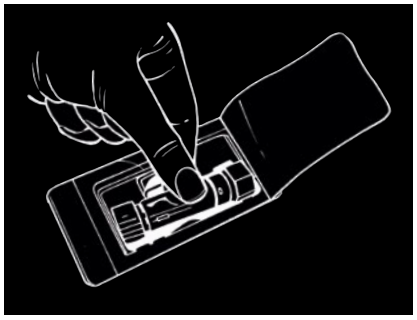
The Packaging

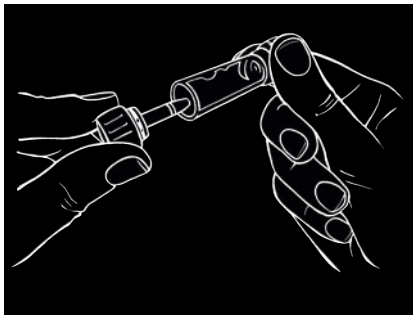
The implant is supplied in a gamma sterilized package which includes the appropriate cover screw.

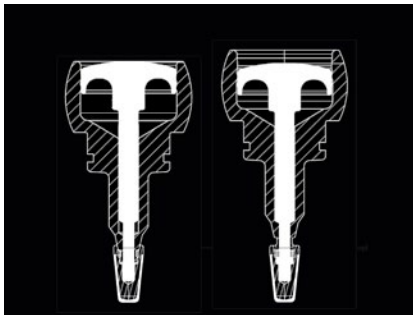
Following the opening of the blister package, the implant and cover screw are kept in separate sterile compartments, which remain sterile until the time for their use.

The OT-F³ implant is mounted on a transport pin with press-out function. This guarantees an easy fixation of the implant in the bone preparation.

Please take additional information from the enclosed instructions for use.







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 implant 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 after exposure of the jaw bone.

An additional aid for diagnosis is the three dimensional 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.

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Prosthetics

Prosthetic Abutments

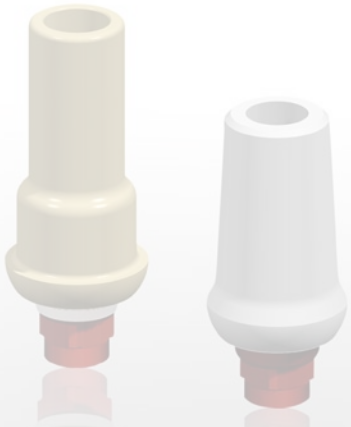
The prosthetic variations of the OT-F³ implant system feature a versatility, but also a simplicity at the same time. The system offers constructions from single tooth replacement to small and also large bridges up to an edentulous jaw reconstruction in different variations. If cemented, screw-fixed or removable by the dentist, the denture may be standard, individually custom-made or highly esthetic, everything is possible.
The definitive prosthetic reconstruction of the implants should be placed after complete healing of the soft tissues.

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 titanium abutment „VersaLine"**
  For the preparation of individual abutments by trimming from the complete piece, especially for the telescope and cone 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.
- **Preform**
  Massive titanium abutment for individual milled titanium abutments by CAD/CAM methods.
- **Ball head abutment „TecLine"**
  For anchorage of complete prostheses with O-ring or Dalbo®
  Plus elliptic attachments
- **LOCATOR® Abutments**
  For anchoring of complete prostheses with original LOCATOR® retention elements (Zest Anchors, USA)

IMPORTANT
All abutments with fixation screw are delivered with the laboratory screw mounted. The color-coded definitive screw is used for final fixation of the abutment in the mouth of the patient with 35 Ncm (except for CreativeLine). CreativeLine should be fixed with 15 Ncm. This screw is contained in the square cover cap of the acrylic vial of the prosthetic packing.

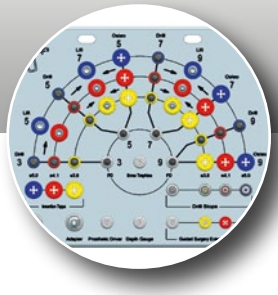
Please see detailed information in the OT-F²/OT-F³ product catalog.

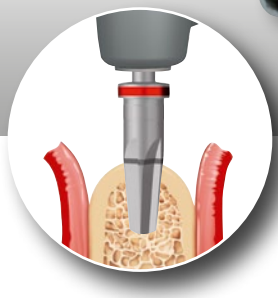


OT-F³ Surgical Tray

Features

- OT-F³ drills of new generation
- simplified and time efficient drill concept
- effective and self-explanatory drill protocol, intuitive handling
- simple positioning of components after use and cleaning





The creatively completely renewed OT-F³ surgical tray offers all components for an implant bed preparation with cutting drills, compressing osteotomes together with all auxiliary tools for insertion of the OT-F³ implants.
The apically concave cutting osteotomes for the internal sinus lift may be added.

The self-explanatory graphics shows the surgical process and facilitates the correct positioning after use and cleaning. The logical positioning of instruments in the compact surgical tray allows intuitive handling and therefore offers easier workflow and a saving of time for user and team.

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OT-F³ Preparation

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.
The Pilot Drills and Final Drills can be used with or without Drill stops.
The use of a drill depth stop ensures a particularly safe drilling procedure. Since this touches down during the preparation at the highest point of the jaw bone, it is necessary on uneven alveolar ridge to do an additional drilling without the depth stop down to the laser marking until the drill has reached the lowest point of the alveolar ridge.

Any bone particles should carefully be preserved and used later for a possibly necessary augmentation which is not in direct contact to the OT-F³ implant (see Introduction page 2). For severely spongeous bone (D4) a stable (compact) implant preparation should be made by compression of the bone particles by using the osteotome technique, avoiding a bone harvesting by drilling in this case.

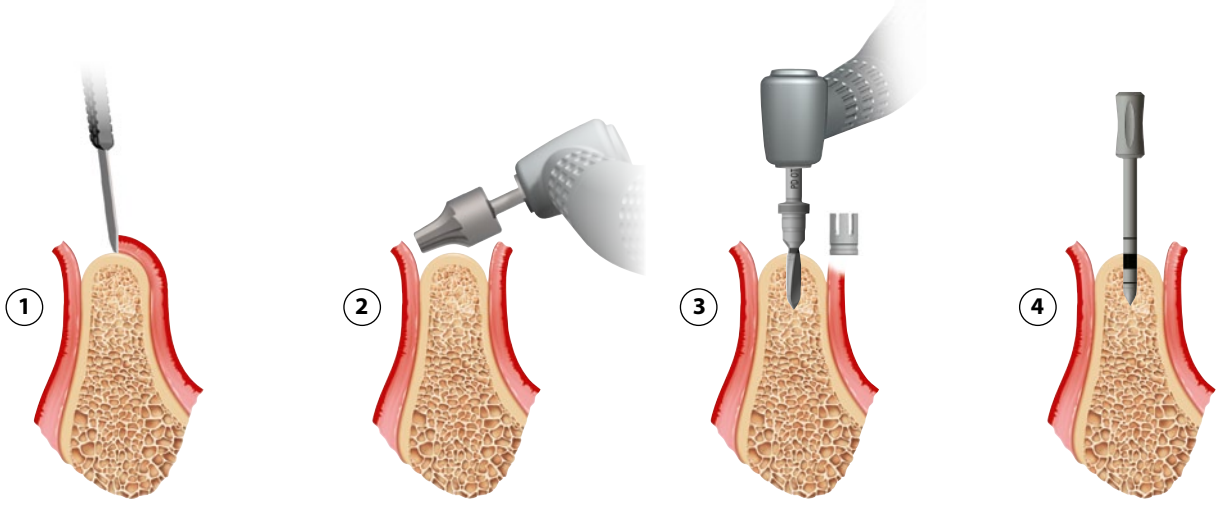
Step 1: Exposure
OT-F³ implants are inserted after exposure of the jaw bone. The doctor decides if individual incisions are required in the present situation.

Step 2: Preparation of the jaw bone
If the exposed alveolar crest shows protrusions which are unfavorable for implant insertion, such as small or even sharp edged ridges, these can be removed by using a bone trephine in order to prepare a plane level for insertion of the implant.

Step 3: Perforation of the cortical bone / Pilot drilling
The first prepraration (oder drilling) to the desired final depth with the length-specific pilot drill [Color coding: grey] (Recommended speed: 1200 rpm).

Step 4: Control check 1
Use the measuring probe to verify the drilling depth achieved compared to the planned drilling depth.

From this point onwards the doctor decides according to the bone quality if an expansion of the implant bone preparation with cutting drills (page 8) or with compressing osteotomes (page 9) is required.



Preparation Drilling

[Drill]

Bone preparation with cutting drills

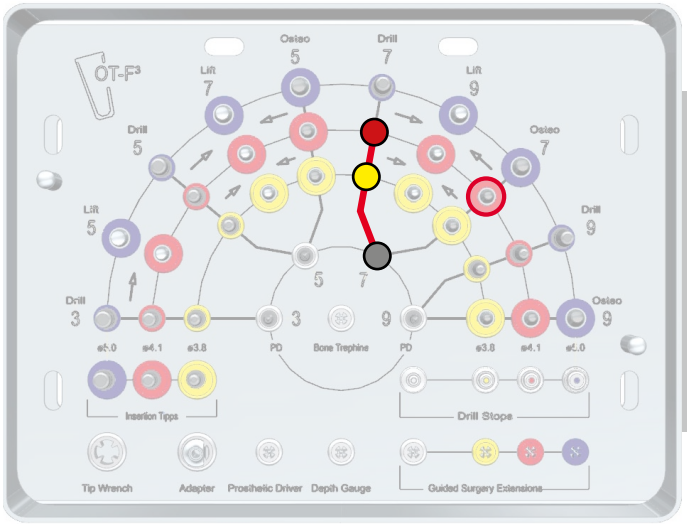
Step 5: Expansion of the preparation
The final drills are slightly underdimensioned to the actual implant diameter. For each implant related on the diameter and length a final drill is available. In surgical tray lines and arrows indicate the sequence of the corresponding drills and osteotomes.

We recommend the following speeds:
Final Drill 3.80 : 950 rpm
Final Drill 4.10 : 900 rpm
Final Drill 5.00 : 850 rpm

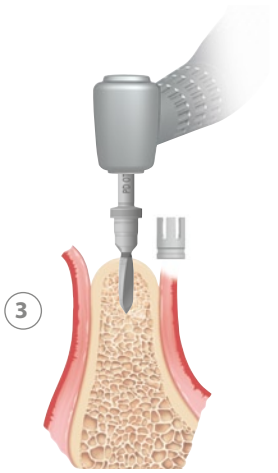
Note

The drills must **not be used more than 15 times** as otherwise optimum cutting action cannot be guaranteed.

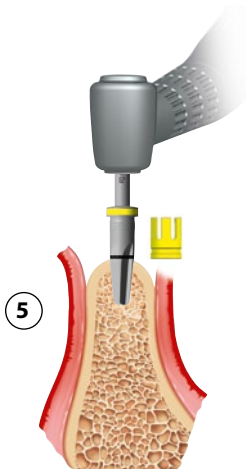
Step 6: Control check 2
To check the prepared implant site, choose the correct trial fit gauge [Osteo] according to diameter and length of the implant and insert it without pressure into the site. The trial fit gauge should be inserted to the upper marking.



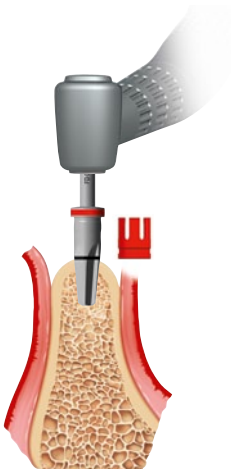
The graphic illustration demonstrates an example for the use of the drills for the insertion of an OT-F³ implant ø 4.1 x 7 mm.



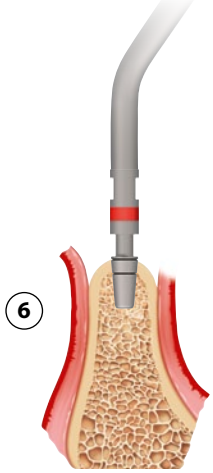
PD L7
shows step 3 (page 7)



FD OT-F3 Ø 3.8 L7



FD OT-F3 Ø 4.1 L7



TFG Ø 4.1 L7

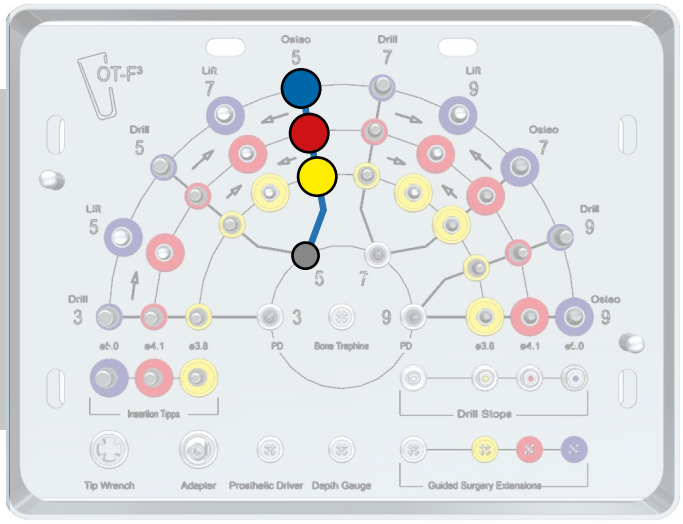
Preparation Osteotomy

[Osteo]

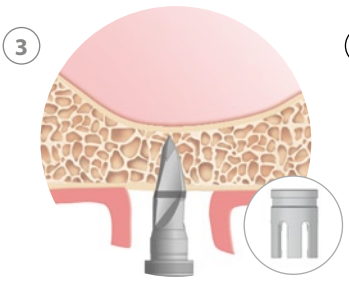
Preparation with compressing osteotomes

Step 5: Step by step expansion with osteotomes
The osteotomes are slightly underdimensioned to the actual implant diameter. For each implant related to the diameter and length, each one osteotome is available.

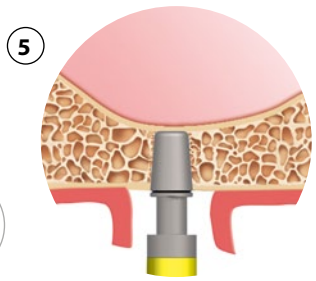
In surgical tray lines and arrows indicate the use of the corresponding drills and osteotomes.



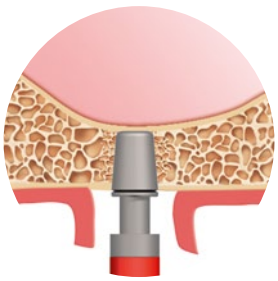
The graphic illustration demonstrates an example for the use of the osteotomes for the insertion of an OT-F³ implant ø 5.0 x 5mm.



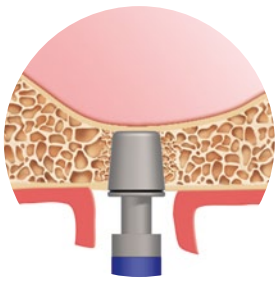
PD L5
shows step 3
(page 7)



TFG Ø 3.8 L5



TFG Ø 4.1 L5



TFG Ø 5.0 L5

Internal Sinus lift

[Lift]

Bone preparation with cutting drills

The doctor will decide according to the available bone quality if an expansion of the implant bed is necessary using cutting drills (described here) or compressing osteotomes (page 11) prior to application of cutting osteotomes.

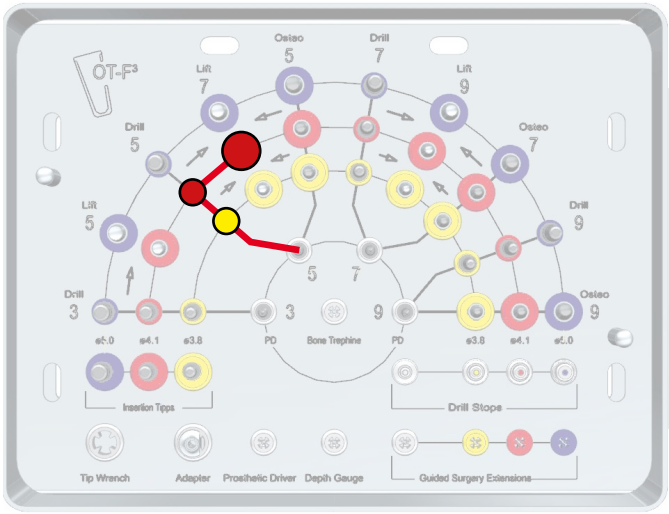
Step 5: Expansion of the bone
The final drills are slightly underdimensioned to the actual implant diameter. For each implant related to the diameter and length, each one final drill is available. In surgical tray lines and arrows indicate the use of the corresponding drills and osteotomes.

We recommend the following speeds:
Final Drill 3.80 : 950 rpm
Final Drill 4.10 : 900 rpm
Final Drill 5.00 : 850 rpm

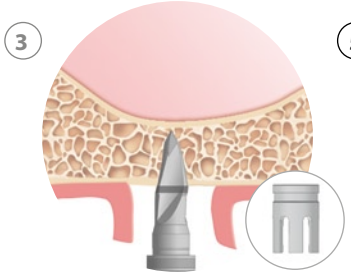
Note

The drills must **not be used more than 15 times** as otherwise optimum cutting action cannot be guaranteed.

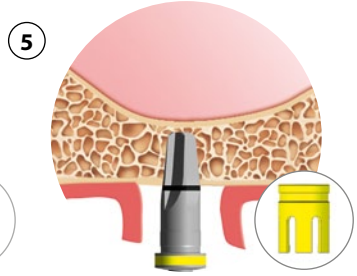
Step 6: Sinus lift
The preparation of the bone should stop close to the cortical floor of the maxillary sinus. Subsequently, the residual bone is then lifted carefully by using the cutting osteotome mechanically with slight tapping (with the osteotome hammer). The OT-F³ implant is placed by using the corresponding color-coded insertion tips with slight tapping to the crestal bone level.



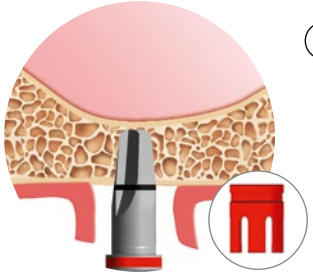
The graphic illustration demonstrates an example for the use of the osteotomes for the insertion of an OT-F³ implant ø 4.1 x 7 mm.



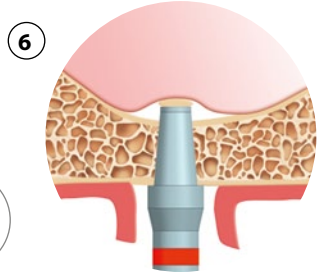
PD L5
shows step 3 (page 7)



FD OT-F3 Ø 3.8 L5



FD OT-F3 Ø 4.1 L5



OS Ø 4.1 L7

Internal Sinus lift

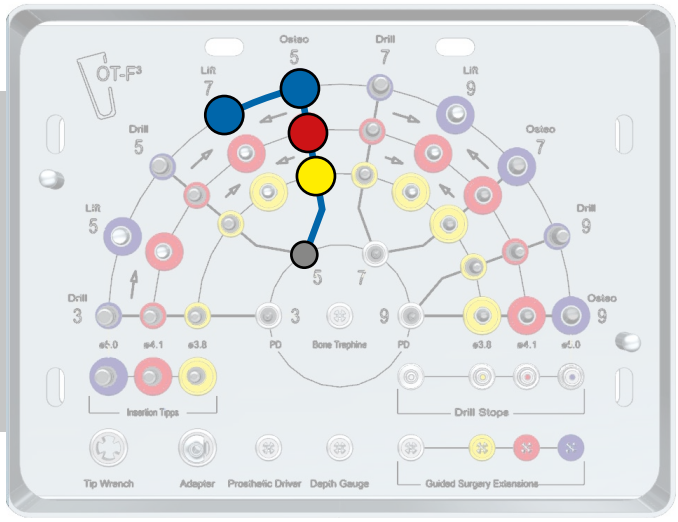
[Lift]

Preparation with compressing osteotomes

The doctor will decide according to the available bone quality if an expansion of the implant bed is necessary using compressing osteotomes (described here) or cutting drills (page 10) prior to application of cutting osteotomes.

Step 5: Step by step expansion with osteotomes
In surgical tray lines and arrows indicate the usage of the drills and osteotomes. For the sequence of the applicable osteotomes - please see below presentation.

Step 6: Sinus lift
The preparation of the bone should stop close to the cortical floor of the maxillary sinus. Subsequently, the residual bone is then lifted carefully by using the cutting osteotome mechanically with slight tapping (with the osteotome hammer). The OT-F³ implant is placed by using the corresponding color-coded insertion tips with slight tapping to the crestal bone level.



The graphic illustration demonstrates an example for the use of the osteotomes for the insertion of an OT-F³ implant ø 5.0 x 7 mm.

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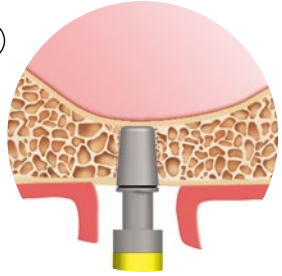
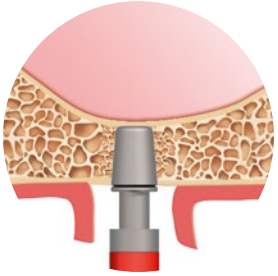


TFG Ø 3.8 L5



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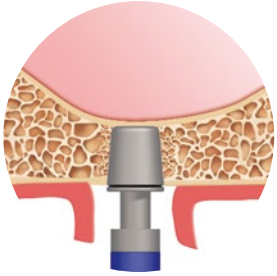

TFG Ø 5.0 L5

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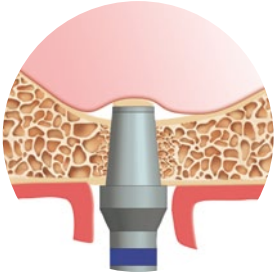


OS Ø 5.0 L7

Insertion

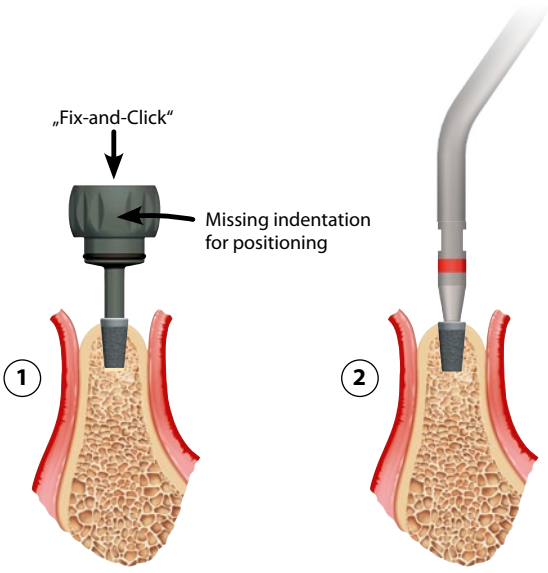
Step by step instructions for the implant insertion

Please take care that the implant when removed from the sterile acrylic vial, does not come into contact with for instance saliva, neighboring teeth, instruments or is contaminated by saline solution. The implant is mounted on a carrier which is connected with the round cover cap.

Step 1: Primary fixation
Remove the implant by pulling off the cover cap from the acrylic vial and place directly into the bone preparation which has filled with blood.

Take note of the position of the FourByFour® internal connection regarding the planned prosthetic restoration with an angulated abutment. One of the missing indentations (see arrow fig. 1) on the cover cap should point into the direction of the planned prosthetic angulation. Stabilize the implant now manually with strong pressure within the implant preparation and then press the "fix-and-click" trigger push-button at the implant carrier until the implant comes off from the pin easily. If necessary, use a corresponding instrument to hold the implant in place.

Step 2: Complete insertion
The further insertion procedure is made with the insertion tips which are mounted on one of the osteotome handles. When selecting the insertion tip, take care that it corresponds with the color coding of the implant to be inserted.
Place now the round head of the tip exactly into the internal contour of the implant. The implant should now be tapped carefully into the preparation by using the osteotome hammer. The implant has reached the final depth when it is ideally level with the alveolar crest.



Healing time

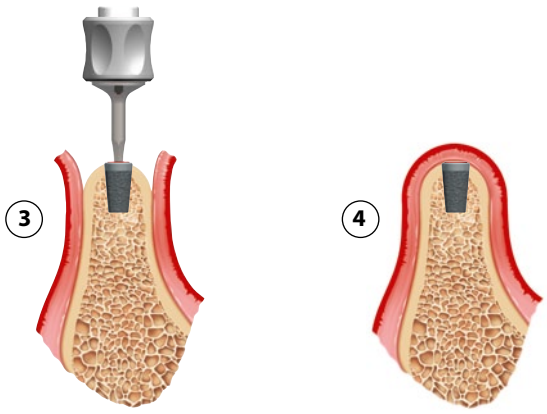
Step 3: Implant coverage
For healing the implant is protected by the cover screw which is contained in the implant package in the square cover cap. Remove the screw by screwing off with the friction-fit insertion key 1.30 mm and cover the inserted implant tightly. Do not exceed a torque of 10 Ncm for tightening the cover screw.

Step 4: 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 D2-D4 (mandible/maxilla)
• age and state of health of the patient
• implant bone preparation (drilling or osteotome technique)
etc.

Principal rule for healing time of implants with sintered surface:
• 3 months in the mandible
• 6 months in the maxilla

For control of the healing process a perio-test check is recommended.



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Exposure of the implants 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 (Fig. 2).
When suturing, care must be taken that the mucous membrane sits tight against the healing abutments.

At this point we recommend:
- the check-up by a perio-test in order to control the osseo-integration
- the 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

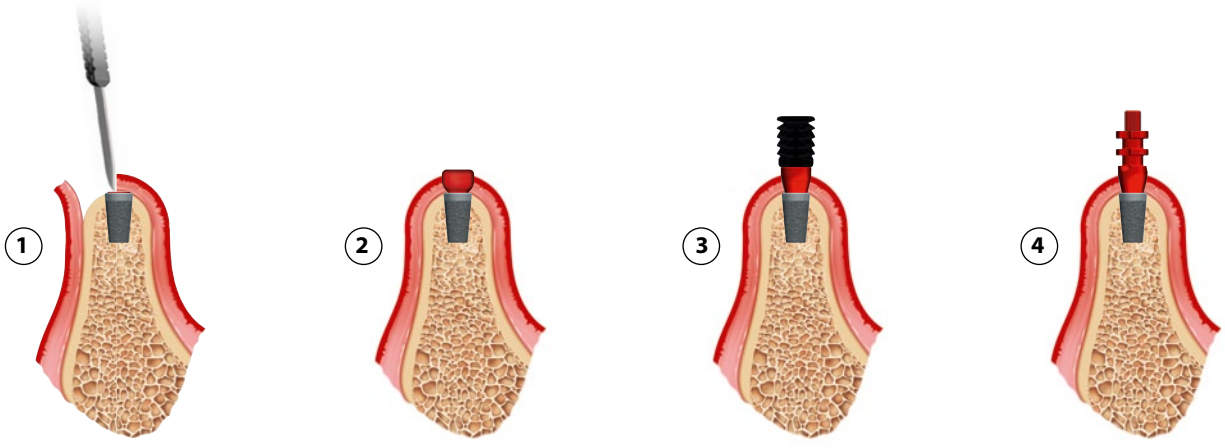
After complete healing of the gingiva, the impression can be taken. The implant system offers a selection between closed (reposition technique) (Fig. 3) and open impression method (pick-up technique) (Fig 4).
Remove the healing abutments, place the impression copings onto the implants and fix with the corresponding fixation screws. The FourByFour® connection provides an exact transfer of the implant position to the master model to be prepared.
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.



For cases which do not indicate the OT-F³ implant

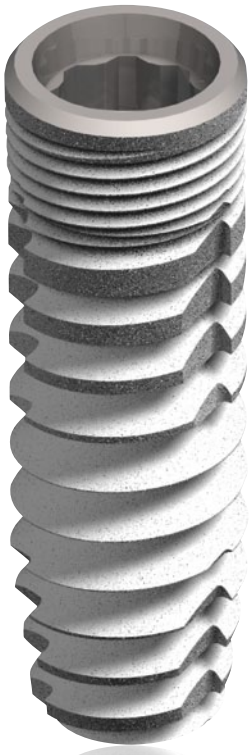
THE OT-F² IMPLANT

The slightly conical micro threads in the crestal area as well as the platform switching are the outstanding modern features of the OT-F² Implant system.
The self tapping compression thread system - optimized by additional cutting notches in the crestal area - leads to a high primary stability.

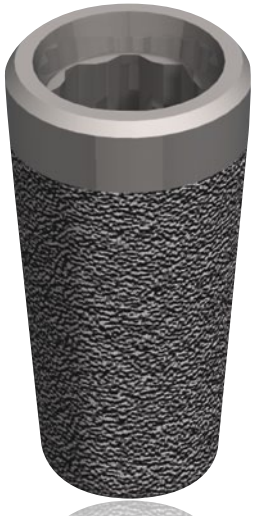
The identical FourByFour® internal connection of the OT-F² screw implant and the OT-F³ press-fit implant combines these implant systems to a comprehensive concept which reliably covers nearly all indications.

The stable internal connection leads to a simple, safe positioning of prosthetic components. Platform switching, cone-shaped entry and a highly precise rotation lock are outstanding features of this modern concept.

The compatibility of both systems OT-F² and OT-F³ regarding prosthetic components is easily understandable and less cost intensive. The prosthetic components assortment contributes to a clear arrangement and user friendliness.



Two compatible systems – one Prosthetic Line



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