



User manual for complete guided surgery

Editorial

With research and development experience since 1988 and clinical experience since 1992, **etk** has a proven track record in implant design confirmed by the invaluable assistance of internationally recognised research laboratories.

The design of our implants is based on the triple competence of a reactive team experienced in implantology:

> The technical and biomechanical skills of our engineers guarantees the durability of the components and their adaptation to oral applications through modern simulation methods.

The biological and physiological know-how of the associated laboratories validate the osseointegration capacity of our systems.

The clinical and practical skills of our dentists and dental technicians ensure the ergonomics of our products, the rationalisation of our protocols and the establishment of ranges adapted to the various clinical cases encountered.

The complete Naturactis Guided Surgery Kit is also based on the most recent advances in scientific knowledge of implant treatment.

In order to make the most of the complete Naturactis Guided Surgery Kit, we have produced this manual with a concern for professionalism and we invite you to read it carefully. The smallest detail is important and underscores all the more the difference between the amateur and the specialist.

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Complete guided surgery is a specific treatment concept, requiring experience with "classical" dental implant dentistry techniques, but also requiring a dual learning:

Computer-assisted implant planning is a revolutionary tool, but one that requires many clinicians to acquire new computer skills.

The coordination between you and your team of assistants must be perfect. Indeed, the particular organisation that accompanies this system can be a source of significant peroperative stress for a new user. It is necessary to train your team and give them as many tasks as possible during your interventions so that you can focus on your main objectives.

The experience of the surgeon is crucial, because they must take matters into their own hands in case events do not go as planned.

The instructions and protocols described here must be implemented exclusively using the components and instruments provided by **etk**. These instructions will guide you through the different phases of your implant treatments. They are accompanied by the most accurate advice possible, but cannot serve as "recipes", since each clinical case is unique. A very large number of factors act interdependently to achieve a successful implant treatment. It is up to the clinician to understand the key principles, and to draw on their clinical experience.

The technical specifications and clinical advice contained in this manual are for guidance purposes only and shall not give rise to any claim. All the essential information is indicated in the package leaflet provided with the products.

We have taken particular care in the design and manufacture of our products; nevertheless, we reserve the right to make changes or improvements to our complete guided surgery system based on new technical developments. You will be notified of any changes that affect the operating procedure. Depending on the extent of these changes, a new manual may be provided. On the back of your user manual, a version number indicates the date of your publication, which makes it possible to check that you always have the latest updates. You will be able to find the current version of this manual on our website. The reproduction and distribution of all or part of this work requires the prior consent of **etk**.

General information ON GUIDED SURGERY NATURACTIS COMPLETE GUIDED SURGERY

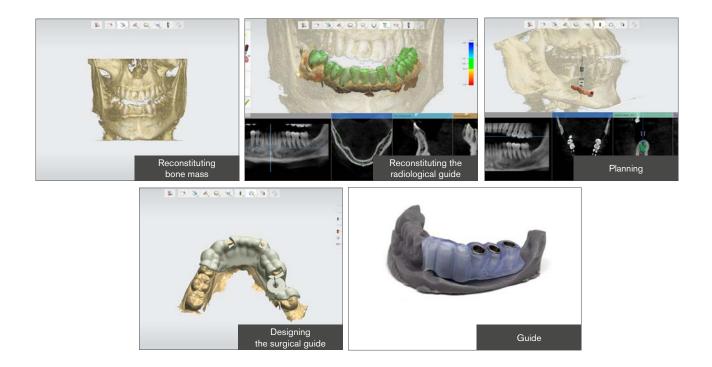
Overview of the CONCEPT

Complete Guided Surgery (CGS) can be defined as the ability to transfer a computer-designed implant planning, based on CT scan (CT, Cone Beam) data, **into the mouth.**

The transition from a virtual project to a surgical reality is possible through a surgical guide created by 3D printing from data of the inside of the prosthesis and data of the implant planning made with the planning software

The advantage of complete guided surgery is undeniable.

In fact, it offers solutions in the field of pre-implant anatomical investigation (a better predictability of anatomical complications) and thus improves the safety of implant surgery. All important decisions can be taken prior to surgery (choice of implant site, size and diameter of implant, etc.).



Major INDICATIONS

Complete guided surgery is a treatment applicable to all indications and offers a wide range of flexible solutions:

- From the single case, partial to total edentulism
- Surgical procedures without incision (flapless technique)
- From immediate loading on a frame to deferred loading
- From prefabricated to conventional prosthetic solutions.

Not to mention that it is indicated when the following criteria are met

- The patient meets all the health requirements allowing a surgical intervention to be performed.
- The healing is complete after a graft protocol.
- Satisfactory bone quantity and quality
- Mouth opening sufficient and appropriate for guided surgical instrumentation.

Advantages and interests of COMPLETE GUIDED SURGERY

Facilitates decision-making for implant treatment with predictable results, as the system is very reliable, allowing for optimal implant positioning with no margin for error.

Study of bone density, which will lead to strategic surgical and prosthetic choices: surgical sequence, number of implants, their position, their angulation, type of prosthesis, etc.

Maximum exploitation of bone volume: no need for timid implantation. Calculation of the volumes to be grafted, which allows the donor site to be chosen.

Precise orientation of the implant in the mesiodistal and labio-lingual direction. Simplifies protocols and increases the success of surgical treatment.

Control of bone grafts, or even in some cases, reduction of graft indications by exploiting the remaining bone volume to the maximum.

Allows perilous or difficult implantations to be performed: search for bicortical supports, lateralisation of the implant path in relation to the dental nerve, etc.

A further step is taken in the case of flapless surgery, which greatly improves postoperative outcomes, thus saving time and providing substantial comfort for the patient.

Possibility of combining the osseointegration period and post-extraction implantation in order to have minimum bone resorption with maximum precision.

Increase patient-practitioner communication.

This system contributes greatly to ensuring better coordination between the various members of the treatment team (clinician, dental technician, laboratory, assistants), because it has the advantage of being an excellent communication tool and therefore one for teamwork.

Limitations OF COMPLETE GUIDED SURGERY

They are mainly technical:

Insufficient and inadequate mouth opening for guided surgical instrumentation.

The anatomy of the site complicates the insertion of the implant and its anchoring.

Need for sufficient available bone height.

The thinness of the bone tables (complete guided surgery requires the existence of an adequate bone quantity and quality).

Hygiene: the patient must be informed and motivated, but must also have the skills to ensure proper maintenance. Those who are uncooperative will be rejected. It is important to note that transmucosal surgery is very demanding in terms of indications. There is a high degree of precision with these guides, but it is not absolute and should not overshadow the introduction of sufficient surgical margins.

PRE-IMPLANTATION STUDY

Feasibility of implant TREATMENT

This study is based on various elements

► An accurate history based on a medical questionnaire filled in by the patient and collected by the practitioner.

A clinical and methodical examination of the patient's mouth.

Biological tests.

A complete radiological file to determine the available bone volumes.

Guide for choosing IMPLANTS

Available bone volume

In the mesiodistal plane

Allow 2 mm between the coils of an implant and the adjacent natural teeth.

Allow 3 mm between the coils of two adjacent implants.

In the vestibular-palatal-lingual direction

Leave, if possible, 1.5 to 2 mm of bone thickness around the vestibular, palatal and lingual surfaces.

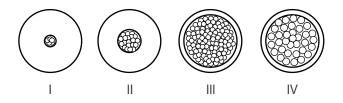
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Ø implant	<mark>0</mark> Ø 3.5	• Ø 4	•Ø4.5

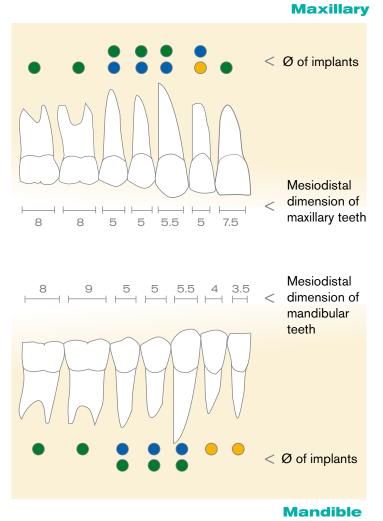
Complete study models with both arches in occlusion.

Implant treatment cannot be initiated until all of the patient's infectious sites have been completely sanitized.

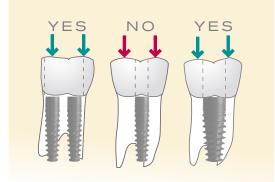
Bone density

Consider the use of larger implants in low density bones to compensate for the loss of bone/implant contact surface due to cavities.





Implant Ø 3.5
Implant Ø 4.5
Implant Ø 4



The LYRAGUIDE SERVICE

LyraGuide is a platform which allows you to make your surgical guides simply and precisely. The development of the guide is carried out in different steps.

Step 1: Making the impression and the Cone Beam

For the elaboration of the surgical guide, you need two digital images: a CT scan to obtain the anatomical constraints essential to perform the guided surgery (width of the bone crest, positioning of the dental nerve, etc.) and a digital impression to locate the position of future dental implants.

- You have an intraoral scanner. Make your impression in the usual way until you obtain the STL file for planning.

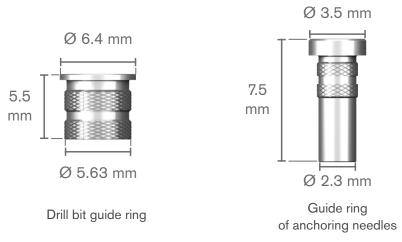
- You do not have an intraoral scanner. Make your silicone impression in the usual way. The cast model of this impression must then be made and CT scanned using a table scanner. Scanning the cast model will provide a STL file for planning.

- Perform the CT scan in a conventional manner as indicated by your equipment. This will provide you with a DICOM file for planning.

Step 2: Implementation of implant planning

- You have implant planning software. Import the STL files (impression) and DICOM files (Cone Beam) into the planning software. Perform the planning according to the anatomical constraints of the patient. Once the implant planning has been completed and the surgical guide modelled, you will obtain the STL file necessary for the impression of the guide.

If you want to add the ring to your open source software, the dimension to indicate are follows :



- You do not have implant planning software. First, please create your account on the platform <u>www.lyraguide</u>. <u>dental</u>. If this is already done, then go to your space and click "Create a new case". You must select the level of service that suits you. Lyra Guide can complete the planning and print the guide or one of the two steps according to your choice. Once the service level is selected, follow the instructions on the form. At the end, you will be asked to import the previously obtained STL and DICOM files. Specialists will carry out the implant planning that you will validate before printing.

Step 3: Printing the surgical guide

- You have a 3D printer. Make an impression of your guide.

Rings are designed to be retained within the guide. However, since each printer is different, we recommend that the printer be set so that the rings fit tightly.

- You have completed the implant planning but you do not have a 3D printer. On the Lyra Guide platform, create a new case and select "Print guide". Follow the form. Import your STL file. Lyra Guide prints your guide.

Step 4: Placement of the guide rings

- You have printed the guide yourself. Insert the rings inside the guide. It may be necessary to apply a drop of glue to properly secure the rings.

- LyraGuide has printed the guide. The **etk** rings are already in place inside the guide. You receive the guide ready to use...

If the case requires the use of anchoring needles, the corresponding rings should be placed in the previously defined locations.

Before starting surgery and after disinfecting the guide, make sure that the surgical guide is properly adapted.

Surgical PREPARATION

Naturactis COMPLETE GUIDED SURGERY KIT

There are two challenges with making implant sockets:

Calibration of the sockets to achieve proper primary stability of the implant, which is essential for osseointegration.
 The clinician is advised to use sharp drills and to perform the drilling under constant irrigation with refrigerated saline solution. Drills have been developed to allow the saline solution to pass through the guide. It is also important to make back-and-forth movements with the drills to optimise the passage of irrigation within the guide.

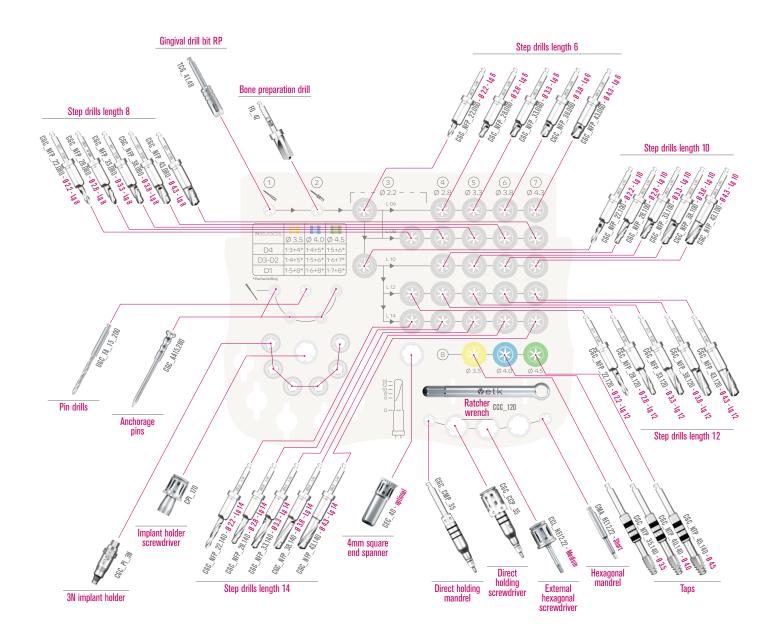
The instruments are presented in their order of use from left to right and from top to bottom.



We recommend that you use a "parachute thread" on the instruments to prevent the accidental fall of tools into the patient's throat. It is important to check that the instruments are held correctly on the contra-angle before they are put into the mouth.

ForetBeyond the quality of irrigation, it is also advisable to use drills whose cutting power has not been altered by excessive use.

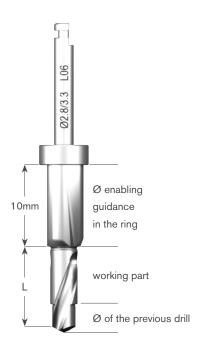
One simple way to ensure that this is done is to count the number of implants inserted by diameter. You will be able to deduce the number of uses of your drills (10 maximum). Be aware that wear varies greatly depending on the type of bone. This kit provides all the necessary tools to complete the guided surgery protocol and to manage all bone densities. It has been designed for the Naturactis implant from \emptyset 3.5 to \emptyset 4.5 and from 6 mm to 14 mm.



Contents of the kit:

- Gingival drill
- Bone drill
- Drill Ø 2.2 stepped at lengths of 6 mm, 8 mm, 10 mm, 12 mm, 14 mm
- > Drill Ø 2.8 stepped at lengths of 6 mm, 8 mm, 10 mm, 12 mm, 14 mm
- Drill Ø 3.3 stepped at lengths of 6 mm, 8 mm, 10 mm, 12 mm, 14 mm
- Drill Ø 3.8 stepped at lengths of 6 mm, 8 mm, 10 mm, 12 mm, 14 mm
- Drill Ø 4.3 stepped at lengths of 6 mm, 8 mm, 10 mm, 12 mm, 14 mm
- ▶ Tap Ø 3.5, Ø 4, Ø 4.5
- Wrenches and direct drive mandrels
- > External hexagonal wrenches and mandrels
- Implant holders
- Implant holder wrench
- Anchoring needles
- Needle drill

SURGICAL preparation



The drills have been designed to ensure guidance from the start of drilling, regardless of the length of the implant selected. The drills are guided by two elements:

> A cylindrical 10 mm portion provides guidance in the ring.

An active stepped portion whose first part corresponds to the diameter of the previous drill.

Positioning of THE TITANIUM RINGS

The positioning of titanium rings on the surgical guide is fixed. The top of the ring is located 10 mm from the neck of the planned implant.

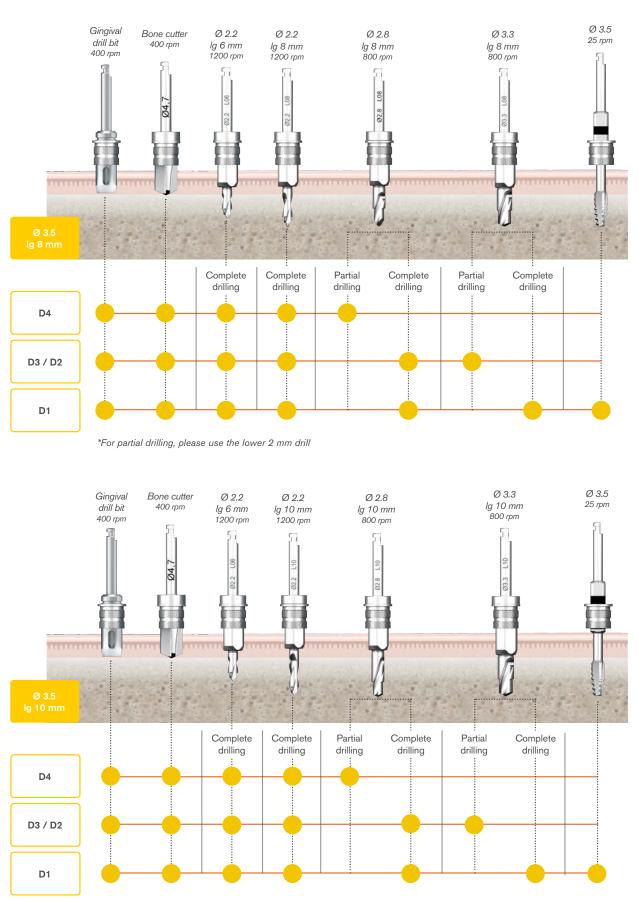




Preparation of THE SURGICAL KIT

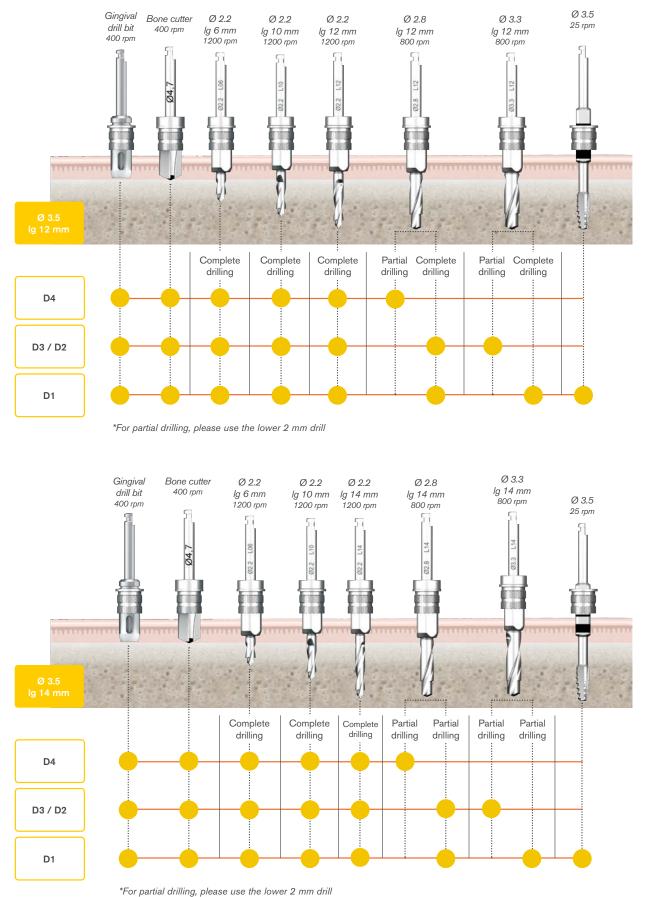
The surgical kit has 6 locations to position the finned tubes containing the implants. This allows the implants to be positioned in the order desired for the implant insertion to be carried out

Surgery FLAPLESS TECHNIQUE

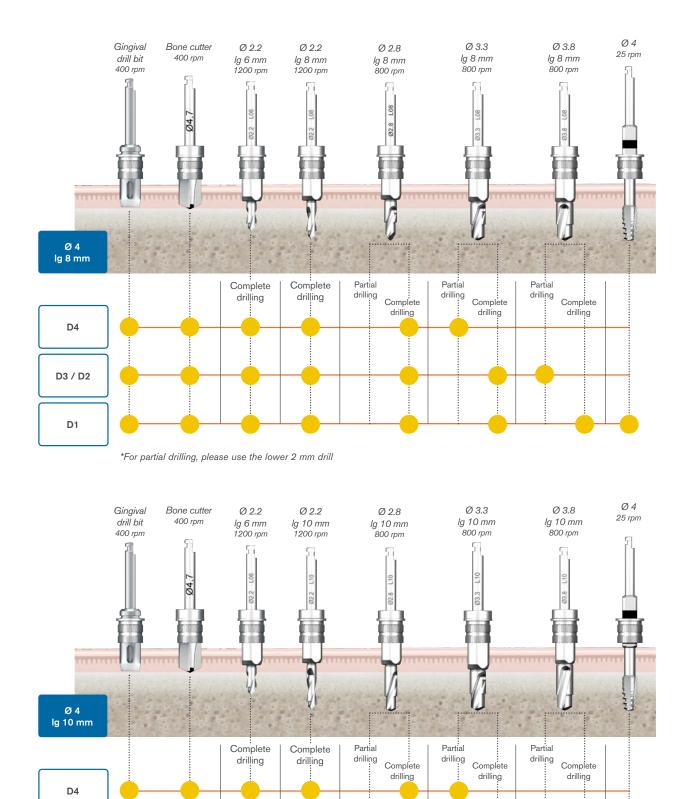


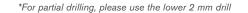
Protocol for complete guided surgery by bone density and implant diameter

*For partial drilling, please use the lower 2 mm drill



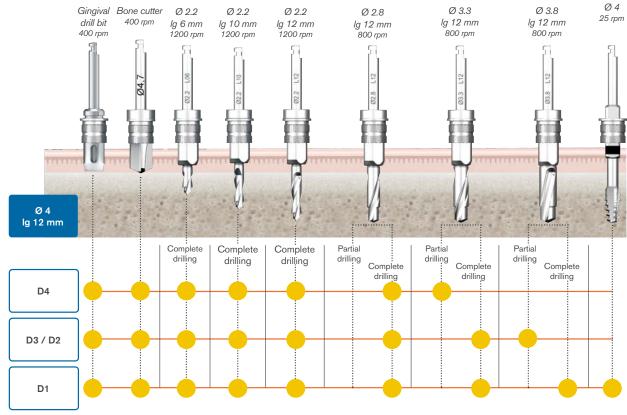
FLAPLESS SURGICAL technique



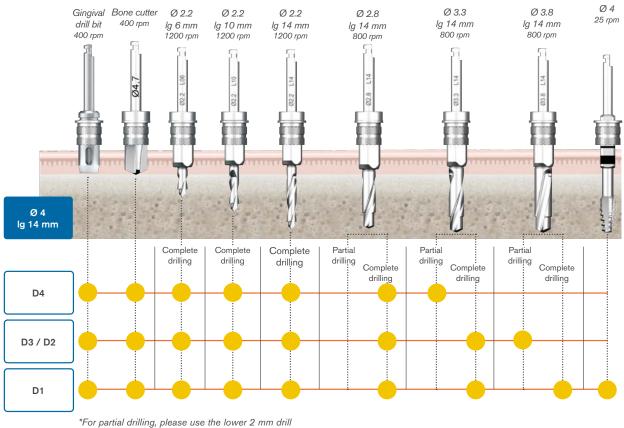


D3 / D2

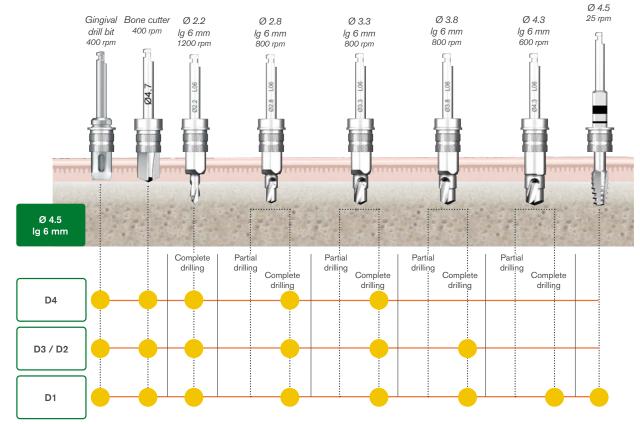
D1



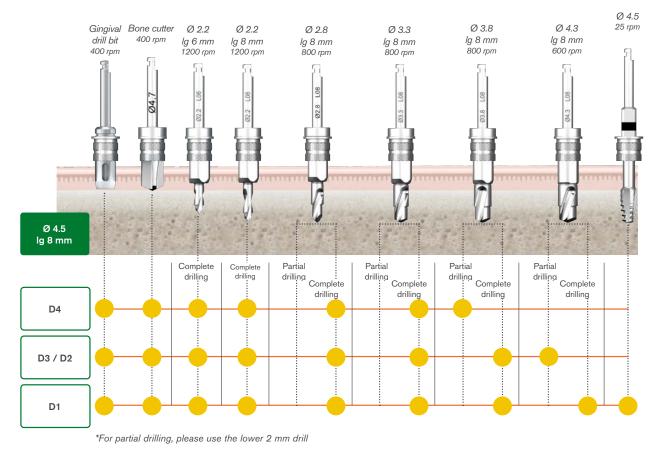
*For partial drilling, please use the lower 2 mm drill

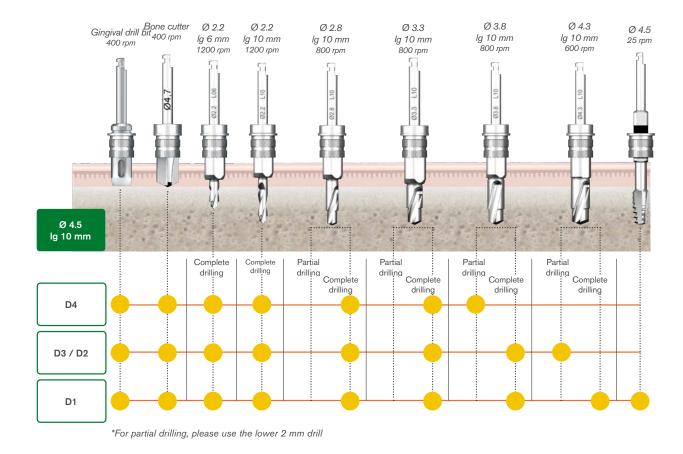


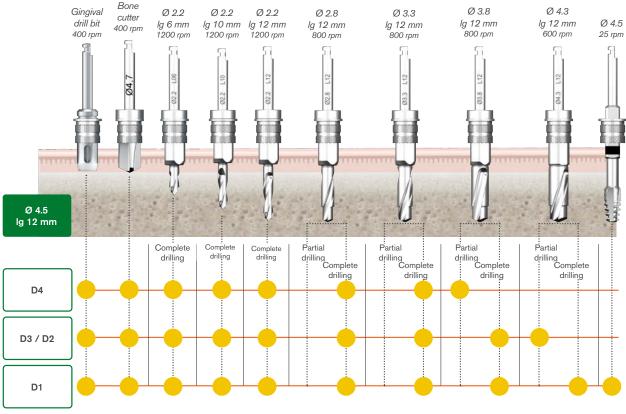
FLAPLESS SURGICAL technique



*For partial drilling, please use the lower 2 mm drill

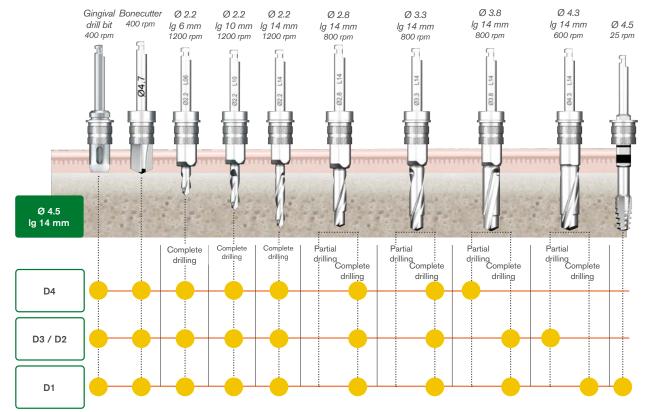






*For partial drilling, please use the lower 2 mm drill

FLAPLESS SURGICAL technique



*For partial drilling, please use the lower 2 mm drill

STEP-BY-STEP SURGICAL protocol

1 - Disinfection of the surgical guide

The surgical guide does not support autoclave sterilisation, only disinfection is possible. Soak it in chlorhexidine for up to 20 minutes, and put it in the mouth quickly.

2 - Check that the surgical guide has good stability

Upon receipt, the surgical guide should be tested in the mouth to ensure its suitability to the patient's anatomy. In the case of a dental support guide, you must check with the display windows that the guide is well-supported on the cuspids of the adjacent teeth.





3 - Application of local anaesthesia

Injections of anaesthetic products must be made at a distance from the support area of the guide. In fact, the anaesthesia stage is a source of mispositioning in relation to the initial project, the local injection of the anaesthetic product creates mucosal tumefactions that are sometimes less noticeable, but that can hinder the insertion of the guide with a dental or mucosal support, or promote its placement in an incorrect position, which can lead to significant instability of the guide, in particular the guide with a mucosal support. Analgesia techniques must be mastered to ensure correct and painless guided surgery.



Photo credit: Dr Ella Bruno (33)

4 - Placement and stabilisation of the surgical guide

To ensure the success of guided surgery, the surgical guide needs to be stabilised. This can be done in two ways. The method of stabilising the guide is to be defined during the design.

By dental or mucosal support:

The guide is placed and stabilised by the teeth or mucous membrane.



By anchoring needles:

The stability of the surgical guide can be achieved using anchoring needles. The position of the needles is decided during the implant planning. The locations of the needles are then printed in the surgical guide in order to guide the \emptyset 1.5 drill for producing the sockets to receive the anchoring needles.





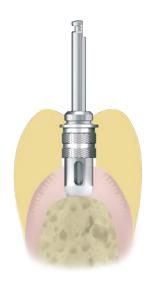


5 - Expulsion of soft tissues

Set motor speed to 400 rpm and start irrigation. The cutting of soft tissue at the site that will receive the implant is done using a self-guided gingival cutter.

Insert the cutter into the ring before putting the contraangle into rotation.

Remove tissues with an appropriate instrument (e.g. a curette) and use a bone drill directly.





6 - Bone crest shaping

Set motor speed to 400 rpm and start irrigation. Insert the self-guided drill into the ring before putting the contra-angle into rotation.

Shape the bone crest to facilitate the guidance of the first drills.

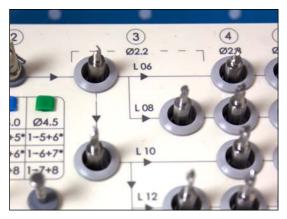
7 - First drill Ø 2.2

The kit contains 3 levels of initial drills of 2.2 mm diameter to ensure guidance of the drills at the start of drilling.

Make sure to follow the arrows indicated on the kit.

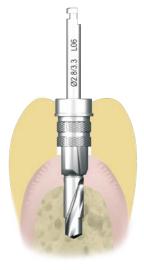
For example, for an implant 14 mm long, you need the 2.2 mm diameter, 6 mm long drill, then the 10 mm long drill, followed by the one that is 14 mm long before continuing to drill directly with the 14 mm long stepped drill. Set the motor speed between 1000 and 1200 rpm. Insert the drill into the ring putting the contra-angle into rotation.

Drill to the fixed drill stop with external irrigation. The drill must



progress without being forced. If not, it indicates that bone debris cannot be extracted by climbing up the helix. A simple, well-controlled back-and-forth rhythm will allow a more fluid progression of the drill. This action does not require a reversal of motor direction if it is performed at the right time. If the drill is blocked, it can be released in "reverse" mode.

It is also important to make back-and-forth movements to cool the tips of the drills inside the guide. When drilling, check that the bone is bleeding. If not, scrape the bone a bit with a probe or curette to make it bleed so that it can pass through the guide ring without compromising the stability of the surgical guide. If there is no vascularization, it is preferable to close and wait for vascularization.



The end of the implant does not fit entirely into the tip of the drill hole. The drill hole made is therefore slightly deeper than the length of the implant (1 mm). This helps to avoid any apical compression.

8 - Additional drilling

Use the diagrams on pages 22 to 29 to determine the range of drills corresponding to the diameter of the selected implant and adapt the implant socket to the bone quality of the site.

When drilling, make sure the bone bleeds.

Otherwise, scratch the bone a little to make it bleed. If there is no vascularization, it is preferable to close and wait for vascularization.

Continue the preparation of the site using self-guided drills at the length corresponding to the implant.

🗥 Partial drilling

In densities D2/D3 and D4, the number of the last stepped drill to be used is marked with an asterisk*. This indicates that the drilling must be partial, i.e. 2 mm shorter than the length of the implant inserted.

To do this, use the shorter length drill. For example, for a 10 mm implant, the 8 mm drill will be used for a partial drilling.

Attention: for implants of 6 mm in length, the drill indicated with an asterisk* (indicating partial drilling) is not to be used.

9 - Tapping

In D1-type bones, it is necessary to preform the implant site for implant insertion.

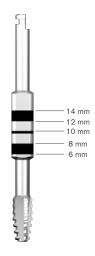
Use the self-guided tap with diameter corresponding to the selected implant.

Place the tap in the implant site (25 rpm)

Exert pressure and begin to turn the tap slowly when the thread engages. Allow the tap to advance under its own effort, without pressure, to the appropriate depth.

Reverse the direction of rotation of the contra-angle and remove the tap.

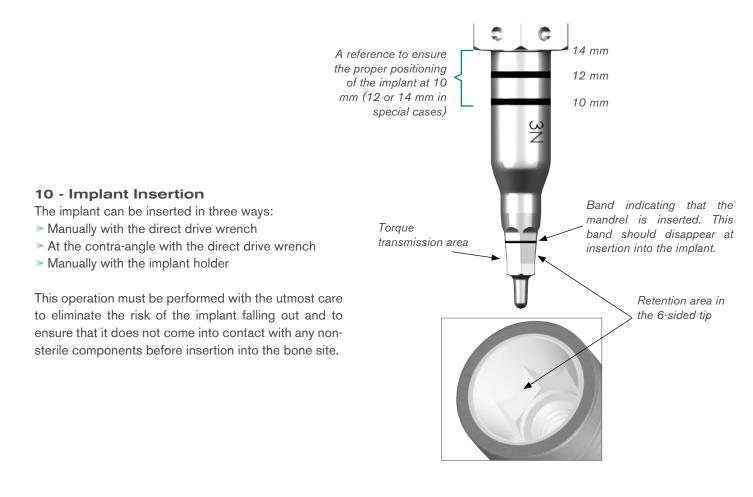




Note 1: the working portion of the tap is 8 mm long.

Note 2: the markers allow the embedding of the tap to be viewed with respect to the adjacent anatomical elements and allows the depth of tapping for long implants to be identified.

Note 3: the depth of tapping can be adjusted according to the quality of the bone and the length of the implant.



10.a - With the direct drive wrench

After opening the sterile tube, connect the end of the wrench or mandrel directly to the implant without removing it from the tube.

Step 1 - Align the hexagon of the mandrel or wrench with the internal hexagon of the implant.

Step 2 - To grasp the implant, rotate the mandrel or the wrench in the implant connection clockwise, until you feel a stop in rotation of the implant in its insert (a device in the insert limits the rotation of the implant during its handling).

Step 3 - Insert the mandrel into the implant while applying a slight force on the mandrel so that it remains on the implant (5 N = 500 g).

a. If the positioning mark is no longer visible, the instrument is inserted correctly into the implant.

b. If the positioning mark is visible, the instrument is not aligned or inserted. In this case, go back to step 1.

c. If the positioning mark is visible, the instrument is not oriented and inserted. In this case, go back to step 2.

Step 4 - With the mandrel well-inserted into the implant, apply a slight counter-clockwise rotation and gently remove the implant from its packaging.

Step 5 - Transport the implant to the receiving site and present it at the entrance of the socket.

Note: Secure your handling against the risk of the implant falling to the ground or into the mouth.

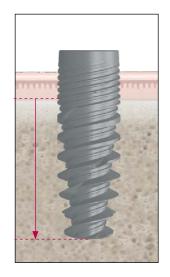
For contra-angle placement, we recommend a speed of 15 to 25 rpm to control the implant descent. The contra-angle placement enables the insertion torque of the implant to be measured, and its primary stability to be determined. We recommend inserting the implant at a minimum of 30 N.cm for delayed loading and more than 40 N.cm for immediate or early functional loading. Do not exceed a torque greater than 70 N.cm.





In a D1 - D2 bone

For a D1 - D2 bone, it is recommended when screwing in the implant to the contra-angle to finish up with a torque wrench in order to ensure the correct implant insertion.



Screw with the contra-angle

10.b - With the implant holder

Implant gripping in the tube should be done as follows:

Step 1 - Place the implant holder in the implant connection. The implant holder has hexagonal indexing.

Step 2 - Screw the screw inside the implant holder to the implant (5 N.cm) to ensure that the implant holder is held on the implant.

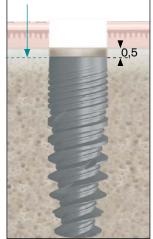
Step 3 - Once the implant holder is secured to the implant, place the wrench provided on the implant holder. The wrench clips on the upper part of the implant holder.

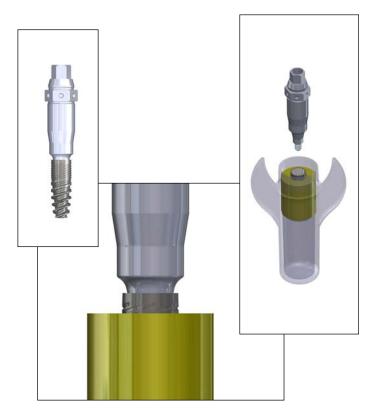
Step 4 - Move the implant to the recipient site and introduce the implant at the entrance of the drilling socket and then insert the implant using the wrench.

We recommend inserting the implant at a minimum of 30 N.cm for delayed loading and more than 40 N.cm for immediate or early functional loading. Do not exceed a torque greater than 70 N.cm.

Once the implants are inserted, remove the implant holders by unscrewing their screws beforehand. Implant holders are used to reinforce the proper support of the guide





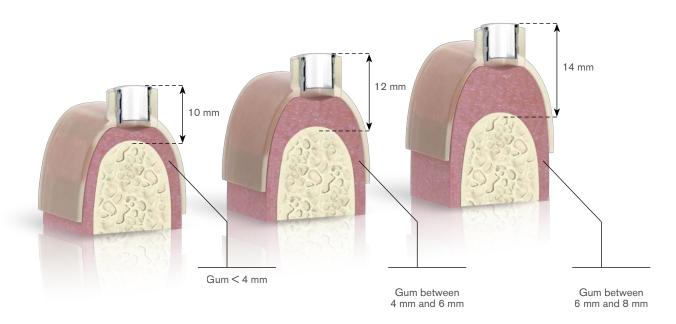


11- Removing the guide

At the end of the procedure, remove the anchoring needles if there are any. Then remove the guide. Excess soft tissue that may interfere with the insertion of the prosthesis can be removed.

Special case: soft tissue that is too thick

The guide ring required for the complete guided surgery is placed 10 mm from the implant neck. In some cases, the gum thickness is too great and does not allow the ring to be positioned at 10 mm. In this case, it can be placed during implant planning at 12 or 14 mm from the implant neck. It will therefore be necessary to use drills 2 or 4 mm longer. Note: In this case, it will not be possible to use implant holders. Also, for a ring positioned 12 mm from the implant neck, it will not be possible to insert a 14 mm implant, as the drills to be used would then have to be 16 mm drills, which are not available in the complete guided surgery kit. Similarly, for a ring positioned at 14 mm, it will not be possible to insert a 12 mm or 14 mm implant.



Protecting the connection

This is ensured:

- Either by iphysio[®] Profile Designer depending on the tooth and the shape of the prosthetic cradle you wish to obtain. For more information on the iphysio[®] Profile Designer, go to <u>iphysio.dental</u>

- Or by a healing abutment if you want to work in 1 surgical step. Select the part according to the shape of the prosthetic cradle you wish to obtain and the prosthetic abutment you wish to use afterwards. Manually screw in the chosen abutment using the external hex key and the torque wrench

to 10 N.cm.

-Or by a cover screw in the case of a 2-step surgery. The screw is supplied with the implant; it is housed in the cap and will be placed on the implant with the external hex key at 10 N.cm. In this case, the site is sutured, taking care not to pull too much on the soft tissue to avoid an operation.

Osseointegration

The usual period for obtaining proper osseointegration is:

- 3 months in the mandible
- 6 months in the maxilla due to different bone quality

The clinician must define this period by taking into account bone quality, primary stability of the implant and the prosthetic plan. In some cases, the clinician may decide to connect the prosthetic parts without waiting for osseointegration. However, the clinician must be able to analyse whether the conditions of the clinical case permit immediate loading.

Studies and scientific data show that immediate functional loading on the mandible is possible when the prosthesis is built on 4 implants connected together. Immediate loading is not recommended on a single-unit implant.

In case of failure

To place an implant, try to unscrew it with the direct drive wrench. If this solution is not sufficient, please refer to the instructions for the extraction kit. The site may possibly be reimplanted*, if the patient is fit to receive a new implant, with an implant of a larger diameter, in the event that the insertion of this implant takes place at the same time. To reimplant the site with a smaller diameter implant, it is advisable to wait for the complete healing of the socket.**

*It is important to analyse the causes of failure before considering possible re-implantation. **The clinician determines whether it is appropriate to use a filling material.



EXTRACTION KIT

KDR_3N

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