



Simplified Guided Surgery User's guide

etk is the result of 20 years of clinical applications and 24 years of research and development confirmed by valuable help of international research laboratories.

The design of our implants is based on the skills of our teams which are both reactive and experienced in implantology:

- ▶ **Technical and biomechanical skills** of our engineers enabling to guarantee the resistance of the component and their adaptation to the oral environment thanks to modern means of simulation.
- ▶ **Biological and physiological skills** of the associated laboratories enabling to validate the capacity of osseointegration of our systems.
- ▶ **Clinical and practical skills** of our dentists advisers ensuring the ergonomics of our products, the confirmation of our protocols and the ranges adapted to the various clinical cases.

Warning	p. 6
I. General information on guided surgery	p. 7 to 9
Presentation of the concept	p. 8
Major indications	p. 8
Advantages and benefits of guided surgery	p. 9
Limits of guided surgery	p. 9
II. Clinical-radiological examinations	p. 11 to 14
III. Surgery	p. 15 to 22
The surgical Kit	p. 16
Flapless technique / flapless surgery	p. 18

Warning

Guided Surgery is a very specific treatment concept, which demands experience of “classic” dental implant technology as well as a dual learning process:

- ▶ Computer assisted implant planning is a revolutionary tool but for many practitioners it means acquiring new computer skills.

- ▶ The coordination between you and your team of assistants must be perfect. And the special organization that goes along with this system can be the source of major per-operative stress for a new user. You need to train your team and offload to them as many tasks as possible during your interventions so you can concentrate on your main objectives.

The surgeon’s experience is paramount as he is the one who needs to take things in hand when events do not happen as anticipated.

The instructions and protocols described here must be implemented in full using the components and instruments provided by etk. These instructions will help you roll out the various phases to be implemented to carry out your implant treatments. They are accompanied by the most precise advice available, but must not be seen as “recipes”, as every clinical case is different. A very large number of factors act independently to achieve a successful implant. It is the practitioner’s responsibility to understand the key principles and to apply his/her clinical experience.

The technical specifications and clinical advice in this manual are purely indicative for the purpose of assistance and cannot be used as grounds for any complaint. All the most important information is in the notice provided with the products.

We have taken great care in the design and production of our products. However, we reserve the right to bring modifications or improvements arising from new technical developments in our implantology system. We will advise of any modifications having an implication in the operation mode. According to the importance of the modifications, a new manual will be issued. Indeed, a mark on the back page indicates the date of issue of your surgery manual, and enables us to check if you have the latest up date version. You will also be able to access our web site to check the latest version of this manual.

The reproduction and distribution of all or part of this manual need previous agreement from **etk**.

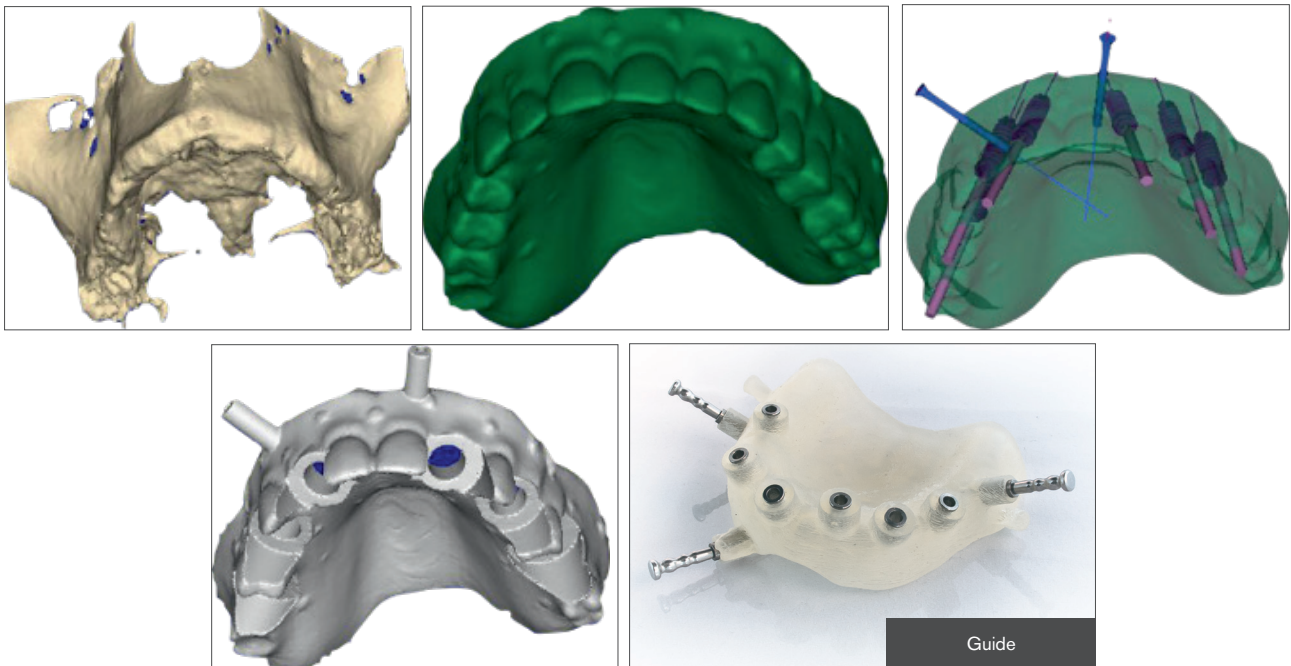
General information ON GUIDED SURGERY

Presentation OF THE CONCEPT

Guided Surgery (GS) can be defined as the possibility of transferring to a mouth an implant plan produced on a computer using data from the tomodontometric examination (scanner, Cone Beam).

The transition from a virtual project to a surgical reality is possible thanks to a surgical guide developed by 3D printing using the data of the prosthetic intrados and the implant plan produced with the planning software.

The benefits of guided surgery are indisputable. It provides a solution for pre-implant anatomical investigation (better prior visibility of anatomical complications) and improves the safety of implant surgery. All the important decisions can be taken into account prior to surgery (choice of implant site, of the size and the diameter of the implant, etc.). Since only the first drilling $\varnothing 2$ is done, any implant type can be then placed by continuing the site preparation with the implant system used.



MAJOR INDICATIONS

It is a treatment concept applicable to all indications and offers a wide range of flexible solutions:

- ▶ A single tooth, partial dentition, or full dentition.
- ▶ Incisionless surgical procedure (flapless technique), with mini-flap, or with flap.
- ▶ Immediate treatment or deferred treatment.
- ▶ A prefabricated prosthetic or a conventional one.

Note that all the following criteria must be met:

- ▶ The patient meets all the necessary health requirements for surgical intervention.
- ▶ Healing is total after a graft procedure.
- ▶ Bone quantity and quality is satisfactory.
- ▶ The mouth opening is large enough and suitable for the surgical instruments.

Advantages and benefits OF GUIDED SURGERY

- ▶ It helps you decide on an implant treatment with the ability to preview the results, as the system is very reliable, allowing optimal positioning of implants with no margin for error.
- ▶ Analysis of bone density: this presents surgical and prosthetic choices: the surgical sequence, the number of implants, their positions, their angulations, their prosthesis type, etc.
- ▶ Maximum use of bone volume: no more timid implantations.
- ▶ Calculate the volumes to be grafted, choose the donor site.
- ▶ Orient the implant precisely mesiodistally and vestibulolingually.
- ▶ Simplify protocols, and increase the surgical treatment success rate.
- ▶ Control bone grafts, and even in some cases reduce graft indications by using the maximum remaining bone volume.
- ▶ Allow perilous or difficult implantations: research bicortical support, lateralization of implant vector compared to the dental nerve...
- ▶ Eliminate an extra step by using flapless surgery, greatly improving surgical outcomes, saving time, and making the procedure much more comfortable for the patient.
- ▶ Combine the osseointegration period and post-extraction implantation to achieve the least bone resorption and maximum precision.
- ▶ Improve patient-practitioner communication.
- ▶ This system greatly contributes to better coordination between the members of the treating team (practitioner, prosthetist, lab, assistants) as it has the advantage of being an excellent communication and therefore work tool for the group.
- ▶ The distance between implants or between implant / tooth is reduced and non compatible with classic guided surgery guides.
- ▶ You can place any type of implant after finishing the bone preparation with a classic surgery system.

Limits OF SIMPLIFIED GUIDED SURGERY

These are mainly technical:

- ▶ The mouth opening must be large enough and suitable for the surgical instruments.
- ▶ The anatomy of the site does not make it difficult to position and anchor the implant.
- ▶ There must be sufficient bone depth.
- ▶ The bone characteristics must be suitable (guided surgery requires adequate bone quantity and quality).
- ▶ Hygiene: the patient must be informed, willing and be able to offer good post-procedure care. Uncooperative patients should be discarded.
- ▶ It is important to emphasize that mucous surgery is extremely demanding in terms of indications. These guides are very precise, but are not absolute and should not detract from ensuring adequate surgical leeway.

Clinical-radiological EXAMINATIONS

Successful guided surgery requires substantial prior clinical and implant experience. The diagnosis must be minutely precise as many factors need to be taken into consideration for the therapy to work:

Patient profile

► General condition

Many important factors must be taken into account when assessing a patient before any implant surgery. A detailed study of the patients' general state of health, their clinical history, their oral hygiene, their motivation and their expectations are an integral part of the pre-operative assessment. It is recommended that a physician be consulted if the patient's clinical history reveals a pre-existing condition or a potential problem that may compromise their treatment and/or well-being.

► Cooperation

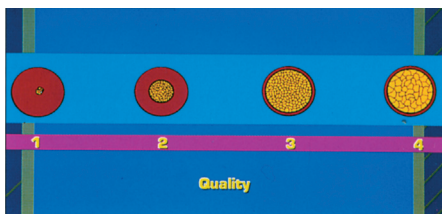
This is necessary during the treatment as strict hygiene is rigorously necessary. To obtain the patient's cooperation, motivation is essential. The practitioner must inform, motivate and teach their patient how to brush and to use each of the personally adapted instruments.

Intra-oral examination

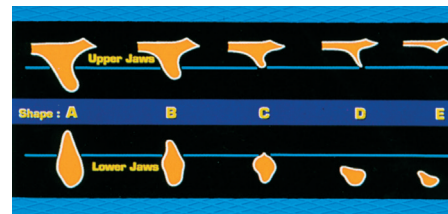
► Bone quality and quantity

The practitioner must determine whether the patient has an acceptable basic anatomy favorable to inserting an implant. The patient must have sufficient bone volume qualitatively and quantitatively. Primary stability is easily obtained with the preservation of cortical bone and minimal bone loss. Most authors report the best success with type I to III bone (Lekholm and Zarb classification) rather than type IV bone.

The classification of osseous structures*



- 1: very high density of compact bone
- 2: thick layer of cortical bone around a dense core of spongy tissue
- 3: thin layer of cortical bone around a big core of spongy tissue
- 4: thin layer of cortical bone around a big core of low density of spongy tissue



- A: important quality of remaining alveolar bone
- B: limited resorption of the alveolar bone crest
- C: important resorption of the alveolar bone crest
- D: beginning of the basal resorption bone
- E: important resorption of the basal bone

* Misch, (1998) Lekholm and Zarb (1985), Classification of partially edentulous arches for implant dentistry.

Some areas must be avoided, in particular when immediate treatment is undertaken as they have a low proportion of trabecular bone. It is therefore more difficult to obtain good primary fixation in these zones. For example, in front of the sinuses in the premaxillary, the bone is type II or III, while behind, in the tuberosity, the bone is often type IV. The surgical procedure must therefore need to be adapted to these low-density zones: under-drilling and search for bi-cortical anchorages.

Furthermore, if a bone fault is present in the cortical bone or if there is a major fault in the trabecular bone, the GS as well as the immediate treatment of the implant can become complicated. This could also contraindicate the insertion of the implant with bone regeneration at the same time.

► **In the vestibulo-lingual sense:**

If possible, leave 2x1 mm of bone thickness (a vestibular and lingual bone wall of 1 mm around the implant).
 - When implants need to be placed in an esthetic sector, the thickness of the vestibular wall must be greater than or equal to 2mm.

► **In the corono-apical sense:**

- In the maxilla: the crestal height necessary is equal to the length of the implant, a penetration of 1 to 2mm in the sinus is tolerated (Nadir et al. 2004)
 - In the mandible: the height necessary is equal to the length of the implant + 2.5mm.
 - Note that bone density is a determining factor in selecting the implant. We recommend using the largest implants in low-density bone in order to compensate for the loss of bone/implant surface contact due to the cavities.

► **In the mesio-distal sense:**

- Ensure 1.5 to 2mm between the external surface of the implant and the adjacent teeth,
 - Ensure 3mm between the external surfaces of two adjacent implants.

Minimum recommended buried length	
Bone quality D1	8 mm
D2	10 - 12 mm
D3	12 - 14 mm
D4	14 mm

Sufficient quantity of keratinized tissue

In the case of deficit at the implant site, a prior arrangement or flap procedure will be necessary to an apical displacement of tissue.

Presence or not of infection

Caution is rigorously required. Healing must be total after a graft procedure, extraction or curettage of an infectious site (curettage of the rest of the periodontal ligament, of a periodontal or periapical infection or granuloma) must be done before the treatment to avoid persistence of residual infection.

An implant treatment cannot be started before complete cleaning of all infectious sites.

(Active) infected sites constitute a contraindication to immediate treatment (De Kok 2006).

Healing potential

It is conditioned by some general diseases such as:

- ▶ Osteoporosis
- ▶ Phosphocalcic disorders
- ▶ Diabetes
- ▶ Hyperparathyroidism
- ▶ Patients who have undergone radiotherapy
- ▶ Weakened immune system
- ▶ Patients who smoke more than ten cigarettes a day...

In these patients, the bone quality and/or healing quality is mediocre.

TMJ, mouth opening and occlusion

The insertion of implants, in particular posterior, requires a sufficiently large mouth opening suitable for the surgical instruments, a 4 to 6 cm opening.

Some TMJ disorders limit the mouth opening and can contraindicate implant insertion. In this respect, condyle travel and opening and closing movements of the mouth must be assessed.

The clinical examination must also determine the presence or not of occlusal anomalies or parafunctional habits, such as bruxism or crossbite. If that is the case, a treatment must be included in the overall treatment plan. The reversibility of the disorder must be determined before inserting implants.

SURGERY

The surgical KIT

The stake for the realization of the implant socket is on two levels:

- ▶ The preparation through the guide of the first drilling \varnothing 2.2 gives the axis and the insertion depth of the implant.
- ▶ Minimum overheating to avoid all irreversible bone necrosis. The socket preparation will be made under constant external irrigation with sodium chloride at 0.9%. The critical temperature threshold is 47°C for 1mn. At 50°C the necrosis is irreversible.

The obtainment of a calibrated socket assuring a good airtightness.

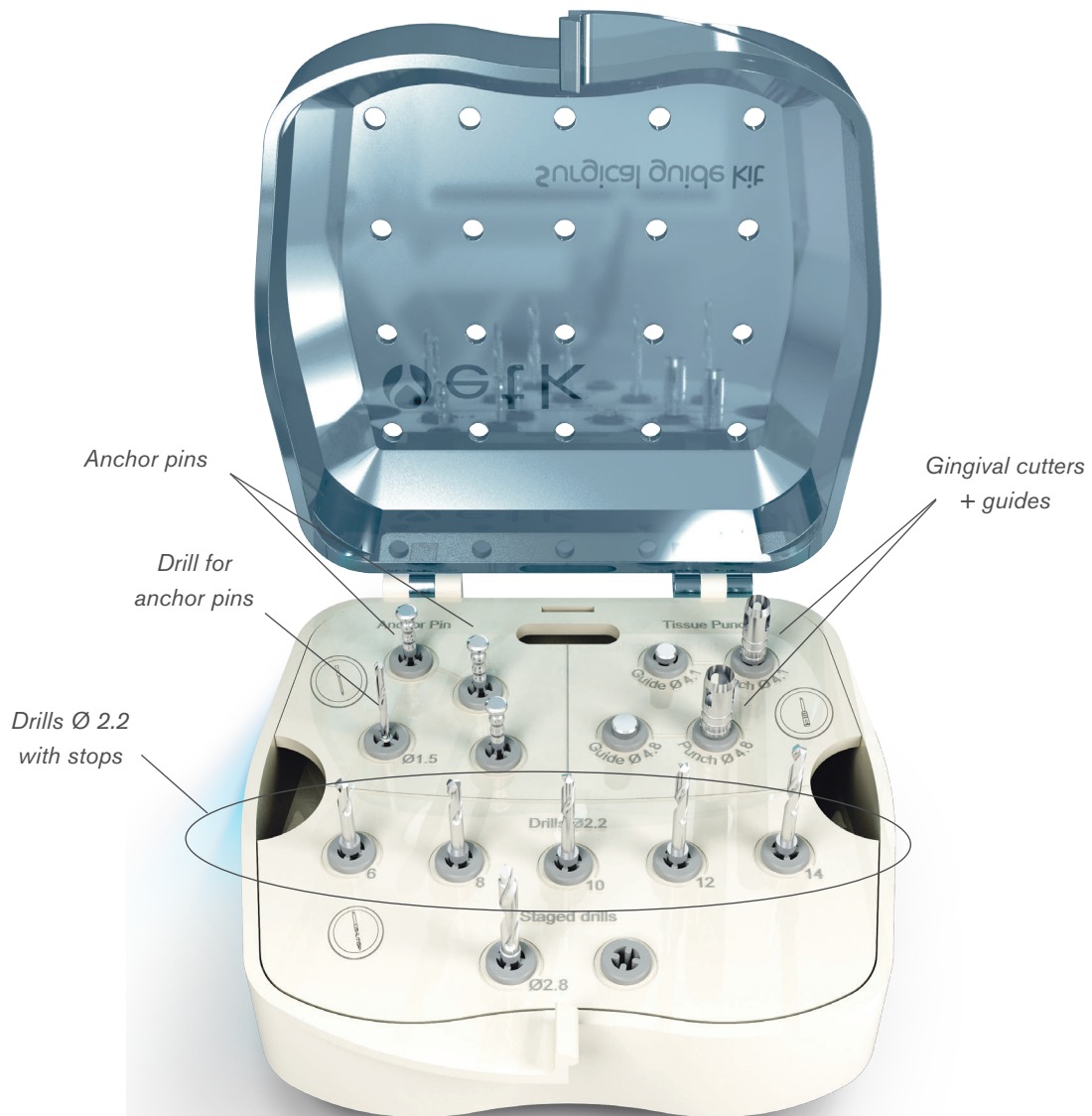
The instruments are sorted by their stage of use as shown by arrows on the kit. Numbers notify the main stops of each stage.

WARNING

The minimum heating will be achieved with irrigation and with a proper selection of drills with a good cutting power. It is therefore necessary to check the number of use of the drills involved in the implant socket preparation. Use the cursors in the surgical kit and change your drills after 10 uses.



This kit contains all the instruments necessary to the guide fixing, the first drilling \varnothing 2.2 and the gingival punch.



Placement OF TITANIUM SLEEVES

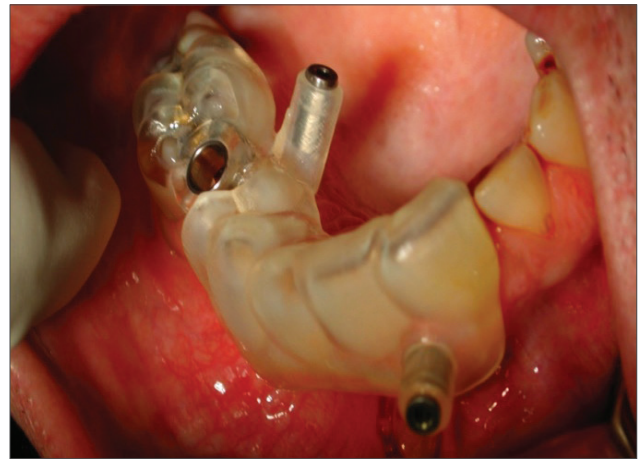
The position of the titanium sleeves on the surgical guide is fixe. The top of the sleeve is 10 mm above of the implant neck.



Flapless TECHNIQUE

1- Verification of the stability of the surgical guide

Once received, the surgical guide should be tried in the mouth to ensure its conformity. It can happen that the guide is not properly adapted, that it wobbles, in which case it must be redone. The surgery must therefore be postponed.



2- Disinfection of the surgical guide

The surgical guide is not sterilizable by autoclave, only disinfection is possible. Soak the guide in the chlorohexidine for maximum 20 mins, then put it in the mouth rapidly.

3- Local anesthesia

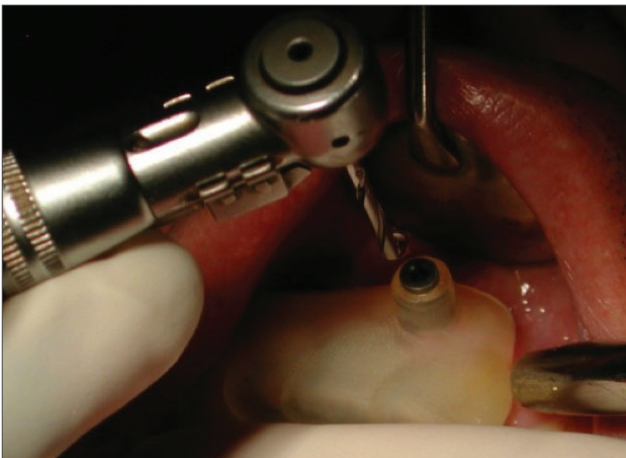
Injections of anesthetics must be **away from the guide support zone**. The anesthesia step is a source of mis-positioning in relation to the intended project. The injection of local anesthetic creates mucous swelling which is sometimes hardly perceptible but which can hinder the insertion of the dental or mucosa-borne guide, or favor incorrect positioning, which can induce great instability of the guide, in particular the mucosa-borne guide.

Analgesic techniques must be mastered to ensure correct and painless guided surgery. This problem does not occur with the bone-borne guide as the flap is created after the anesthesia step.



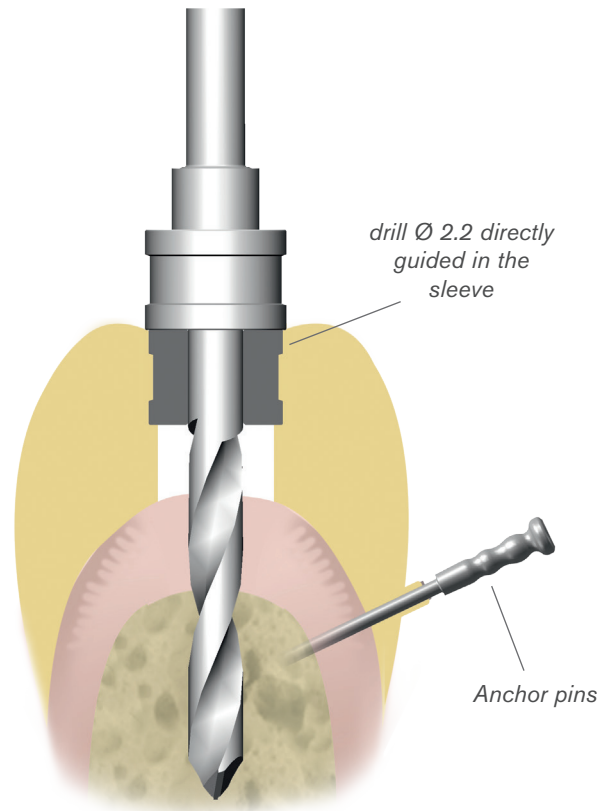
4- Stabilization of the surgical guide

The guide is stabilized by placing three anchoring needles, after preparing the sites for them with the $\varnothing 1.5$ drill at 1.000 rpm.



5- Initial drilling through the guide

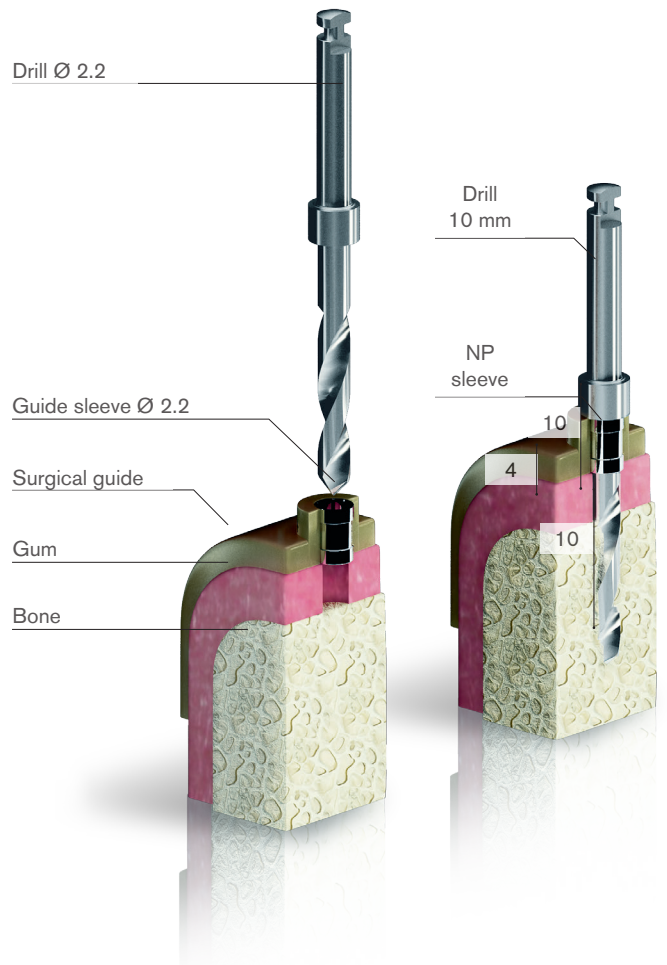
Choice of the length of the Ø 2.2 mm drill The preparatory drilling is to determine the axis and the depth of implant sockets.



The Ø 2.2 drills have stops, and come in five different lengths: 6-8-10-12-14 mm.

Drill until the fixed stop, under constant irrigation with sodium chloride, at a speed of 1000 rpm. Do not force the drill. If it binds it indicates that bone debris is not exiting up the flutes. A carefully controlled simple back-&-forth movement creates easy drilling. Doing this at the right moment avoids needing to reverse the motor. If the drill is stuck, it can be released by using "reverse" mode.

It is also important to make back-&-forth movements to keep the drill tip cool inside the guide.



For example, on a implant 10 mm long following the gum height

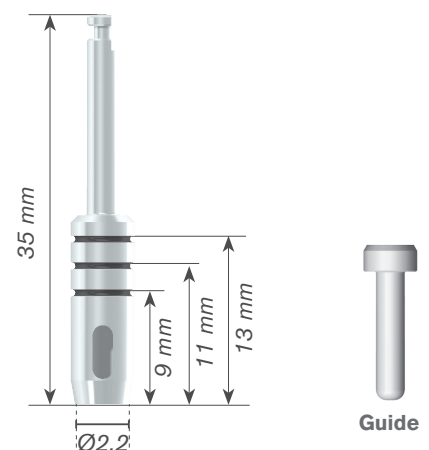
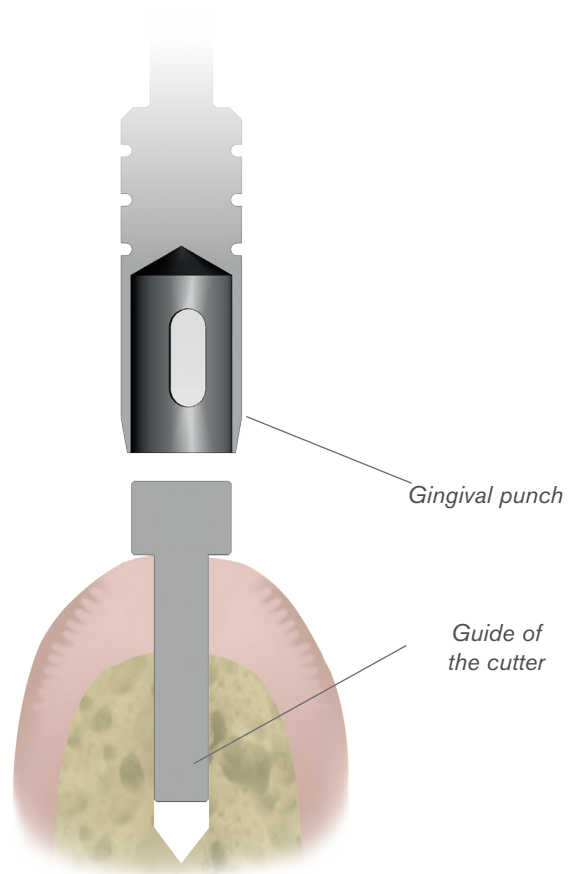
6- Removal of the guide

At the end of the intervention, the guide is removed and any excess mucous tissue that may hamper the insertion of the prosthesis is removed.

7- Removal of soft tissue

Setting of the gingival punch guiding tool, and passing the gingival punch.

Set the motor speed at 400 rpm with irrigation.
The implant site soft tissue is removed with the gingival punch.



8- Preparation of the implant sites and implant placement

Continue the implant site preparation with the traditional surgery kit of the used system.

9- Osseointegration

The conventional period to obtain a good osseointegration is:

- 3 months in the mandibular
- 6 months in the maxilla due to a softer bone

The dentist should define this period by taking into account the bone quality, the implant primary stability and the prosthetic plan.

In certain cases, the dentist can decide to connect the prosthetic parts without waiting for the osseointegration. However, the dentist must be able to analyze if the conditions of the clinical case are appropriate to an immediate loading.

In case of failure

To remove an implant, use a trephine with a greater diameter than the placed implant and remove the bone cylinder obtained. Implant removal is facilitated by using an implant-holder screwed on the implant.

The socket can possibly be re-implanted:

- if the patient is fit to receive a new implant,
- with an implant of wider diameter, in the case that the

Studies and scientific data indicate that immediate loading has proven to be successful at the mandibular when the prosthesis is built on 4 implants or more linked together. Immediate loading is not recommended on single.

The drilling sequence that we propose is a standard sequence that must be adapted to suit the patient's bone quality (density) and implant site.

To put another implant with a smaller diameter, it is better to wait for the complete healing of the socket.

It is important to analyse the reasons of the failure before placing a new implant.

The doctor decides whether it is necessary to use bone material to fill in the socket.

STUDIES & PUBLICATIONS

Analyse comparative de l'état de surface des implants Euroteknika, Straumann, Nobel, Zimmer, Astra - analyse de la topographie de surface (mesure et homogénéité des impacts, identification des molécules présentes à la surface de l'implant) - University of Barcelona - Consejo Superior de Investigaciones Cientificas - **Dr Lluís Giner - Dr Josep Miquel - Dr Jordi Ferre** - 2007.

Analyse de la répartition des contraintes autour des assemblages implants/pièces prothétiques mis en fonction sur une mandibule dynamique à déformation élastique - analyse de la répartition des contraintes - évaluation de la résistance mécanique des éléments - University of Otago, Dunedin, New Zealand - 2007.

Etude de l'étanchéité des connexions internes et externes - analyse au microscope à balayage électronique des ajustements implants/pièce prothétiques - test du bleu de bromofenol sur des éléments enfermés à l'intérieur des assemblages, recherche d'éventuelles micro-infiltrations - University of Barcelona - **Dr Josep Cabratosa Termes - Dra Zaira Martinez Vargas** - 2007.

Intérêt des BETA TCP dans les greffes intra-sinusiennes mixtes à visée implantaire - analyse histologique de l'interface os-implant sur les implants Aesthetica - Université d'Angers - **Dr Bernard Guillaume** - 2007.

Effect of lactoferrin on osseo-integration & bone healing around the Aesthetica implant - Cukurova University / Turkey - **Dr Mehmet Kurkcu** - 2007.

Les prothèses ostéo-intégrées - Brånemark / Zarb / Albrektsson - Quintessence

Osseointegrated implants in the treatment of the edentulous jaw - Experience from a 10 years period. Brånemark / Hansson / Adell / Breine / Lindstrom / Hallen / Ohman - Almqvist and Wiksell international - Stockholm

The Brånemark osseointegrated implant - Albrektsson / Zarb - Quintessence

Osseointegration in oral rehabilitation - Naert / Jan Steenberghe / Worthington - Quintessence

L'implantation en 1985 - Désespoir ou des espoirs ? Analyse exhaustive de la méthode de Brånemark - Expérience clinique de 5 années - G. Huré - Encyclopédie médico-chirurgicale Odontologie 9 -1989 23345 A10

Thérapeutique implantaire Endo-osseuse originale - Le site Tubero-ptyergoïdien - G. Huré - Les cahiers de prothèse n°67 - Septembre 1989

À propos de l'état de surface des implants en titane pur - G. Huré - Implantodontie - 1994 - n°14/15

Comment choisir un anesthésique en odonto-stomatologie - Société d'Anatomie et de Pathologie Oro-faciale - Docteur J. François GAUDY - Maître de conférence service d'Anatomie - Faculté de chirurgie dentaire de Paris V

Les bases buccale - Anesthésie Infiltrations locales d'articaïne associées à une analgésie - Intraveineuse en chirurgie buccale chez les malades à risque - B. Lefevre, D. Lepine, D. Perrin, G. Malka - Le chirurgien dentiste de France - N°566 - 23 Mai 1991

Implantologie orale 2003 - Commission des dispositifs médicaux de l'ADF

Facteurs de risques en implantologie - F. Renouard

Vers un implant universel - Marcel G. Le Gall, André P. Saadoun, Nicolas Le Gall - Implantologie, Février 2005

Platform switching : un nouveau concept implantaire de contrôle des niveaux osseux après mise en charge - Richard J. Lazzara, Stophan S. Porter - PDR volume 26 n°1, 2006

In vitro evaluation of the implant-abutment bacterial seal: locking taper system - S. Didart, M. Warbington, M. Fan Su, Z. Skobe - The international journal of oral & maxillofacial implants 2005; 10:732-737

Étude de suivi clinique sur 10 ans d'implants avec projetat de dioxyde de titane - L. Rasmussen, J. Roos, H. Bystedt - Implant / volume 12 - n°2 - 2006

Le col de l'implant : doit-il être lisse ou muni d'éléments de rétention ? Une étude par la méthode des éléments finis - S. Hansson - Implant / volume 6 - n°2 - 06/2000

Carl Mitch, Francisco H., Nociti J.R., k. Al-Shammari, J. Steingenga, Dr Hom-Lay Wang - J. Periodontol 2004; 75 : 1233-1241

Kim WT & al J. Korean - Assoc Oral Maxillofac Surg 2001 Apr. 27 (2) : 111-117

Risque hémorragique - ARNAL H. - Information dentaire n°12 - Mars 2005

«La péri-implantite en 2008» - ASSEMAT - TESSANDIER X et Coll. - Implant - Vol. 14 n°3 - 2008

«Le canal mandibulaire : un stress en implantologie mandibulaire postérieur» - AUDRY P.C. Thèse Odontologie - Reims - 2009

«Le Site donneur mandibulaire postérieur» - BENOIT PHILIPPE - Information dentaire n°18 - Mars 2006

«Complications et échecs en implantologie» - BERT Marc - Edition CDP - 1993

«Le risque infectieux : la péri-implantite» - BIOSE DUPLAN MARTINI - Information dentaire n°12 - Mars 2009

«Implantologie et patients à risque» - CAMPANA F. et Coll. - Revue implantologie - Mai 2008

«Prévention et traitement des péri-implantites» - CHARGE L. - Revue implantologie - Nov. 2008

«Analyse des échecs implantaires en pratique libérale» - COLIN Ph. - Hors série IMPLANT - Les échecs - 2008

«Echecs et complications en implantologie» - DAVARPANA M. et Coll. - Le Fil Dentaire n°11 - Mars 2006

«Collaboration entre ORL et implantologie» - DOUGE T. - VERNEULEM J. - Revue Implantologie - Fév. 2008

«Les augmentations osseuses complexes et les reconstructions en 3D» - JABBOUR M. et Coll. - IMPLANT - Vol. 14 n°4 - 2008

Report of the Sinus Consensus Conference of 1993 - JANSENOT et Coll. - Int. J. Oral Maxillofacial Implantology - 1993

Condition de réalisation des actes d'implantologie orale : environnement technique - Haute Autorité de Santé - Juillet 2008

«Gestion des complications implantaires» - LOUISE F. - J.P.I.O. 2005

«Expertise ORL pré-implantaire : quand la demander ?» - MAAREK H. - IMPLANT - Vol. 14 n°3 - 2008

«Les Thérapeutiques parodontales et implantaires» - MATTOU PAUL - Quintessence - 2003

«Un cas de fracture implantaire - Observation Clinique et en microscopie électronique à balayage» - MATTOU PAUL et Coll. - IMPLANT - Vol. 8 n°1 - 2002

«Peut-on placer des implants chez un patient sous biphosphonals ?» - MILLIEZ S. - Information dentaire n°12 - Mars 2009

«Complications post-implantaires : gestion et présentation» - MAAREK HARRY - IMPLANT Vol. 15 n°1 - 2009

«Les échecs en implantologie» - PANIS - ROUZIER - Thèse Doctorat en Odontologie - Montpellier 2006

«Facteurs de risques en chirurgie implantaire» - RENOARD F. - J.P.I.O. n°3 - 1998

«Rapport du Conseil Médical du SOU. Médical» - SICOT C. - Groupe MACSF sur l'exercice 2005

«Les reconstructions osseuses en implantologie» - SOLYOM ERIC et Coll. - Revue implantologie - Mai 2008

«Risques anatomiques à la mandibule en chirurgie implantaire» - Stophan G. et Coll. - IMPLANT Vol. 12 n°1 - 2006

«Evaluation quantitative de la réussite implantaire» - TOLOMEO BIOLI L. et Coll. - IMPLANT Vol. 7 n°4 - 2001