



User's guide
Obi Ø2.7

Surgery and Prosthesis

etk is the result of 23 years of clinical applications and 27 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.

The OBI type implant has 30 years of clinical experience. The first implants of this small size (< 3 mm) were placed in the USA in 1976. The OBI implant was inspired by numerous concepts from the evidence of the implants of larger diameter (asymmetrical thread, flared neck), it is a very useful addition to your current system.

To enable you to take the best advantage of the OBI implant, we created this manual with a professional care. We invite you to read it with your best attention. Each detail, even the least important, has its importance and underlines even more the difference between the beginner and the specialist.

Warning	p. 6
General information	p. 07 to 10
Pre-implant study	p. 11 to 14
Surgery	p. 15 to 22
SURGICAL KIT PRESENTATION	p. 16
IMPLANT SITE PREPARATION	p. 17
IMPLANTS PRESENTATION	p. 18
SURGICAL PROTOCOL	p. 19
The prosthesis	p. 23 to 24
OVERDENTURE STABILIZATION	p. 24

The placement of **etk** implants must be done by a practitioner who has been previously trained for the dental implantology techniques and in aseptic conditions specific to this type of treatment.

The following instructions will guide you throughout the different stages of your implantology treatments. They contain advice as precise as possible but cannot be used as «recipes», every clinical situation must be evaluated for each patient. A great number of factors acts independently to obtain success in an implantology treatment. It is up to the practitioner to recognize the key factors and to use his clinical experience. Among other aspects, the coordination between the prosthesis laboratory dental technician and the practitioner must be perfect so as to give the global treatment plan more consisting. Only the practitioner remains responsible for his different choices and decisions as to the treatment's feasibility, implants, prosthetic parts, materials used and settings... The technical specifications and clinical advice in this manual are given solely as a guideline and cannot give rise to any claims. All the essential information is indicated in the instruction for use supplied with 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

IMPLANT preferred usages

- ✦ Lack of retention of a prosthesis
- ✦ Instability of a prosthesis
- ✦ Functional discomfort with the prosthesis
- ✦ Psychological refusal of the wearing of a prosthesis
- ✦ Parafunctional practices which compromise the stability of a prosthesis
- ✦ Inadequate localization and number of remaining abutments

The OBI implant is a transmucosal implant

Conceived to be placed in one surgical operation; its characteristics give it a greater primary stability so as to perform immediate loading when the practitioner consider that all the necessary conditions for this sort of accelerated treatment are present.

Overdentures stabilization

On the narrow alveolar ridges, and patients unable to afford full sized root form implants, or prefer not to have several surgeries, 2 to 4 OBI implants enable to stabilize an overdenture.

Temporary implant

Their small diameters allow the practitioner to place mini-implants between definitive implants within the same surgical time.

Whereas the latter will be buried, mini-implants will allow a provisory prosthesis to be seated, thus bringing an esthetic solution to the patient while respecting necessary time for osseointegration of main implants.

Contra indications FOR USE OF THE IMPLANTS (REMINDER)

Absolute contra indications

- ✦ Major psychological disorders
- ✦ Risky cardiopathy
- ✦ Uncontrolled systemic pathology
- ✦ Alcoholism or medicinal drugs addiction
- ✦ Age of the patient (young patient during growth)
- ✦ Poor hygiene of the patient

Relative contra indications

They are represented by:

- ✦ Insufficient volume and / or an osseous quality
- ✦ A patient presenting risks (patient exposed to atomic radiation, bruxism, uncontrolled parodontitis, addiction to smoking)

Guarantee

In case of non osseointegration, you must inform your commercial representative so that we can examine the causes for the failure and bring the necessary corrective actions. An exchange may take place when the defect of the product is established; if the failure results from

an incorrect clinical analysis, a surgical protocol not adapted to the case, from the use of blunt drills...or for any other reason independant from the product quality, the guarantee will not be taken into consideration.

Precautionary MEASURES

It is strongly advised to keep in stock, implants which cover the most frequently used diameters as well as the different lengths.

It is important to be able to correct an implant's choice during a procedure, to replace an implant which has been contaminated for any reason, to fit an extra implant in certain cases to insure the long term treatment success...

We recommend the use of a safety system (floss attached to instruments or a suitable throat protection system) on the instruments in case of accidental dropping of tools in the patient's throat.

It is strongly advised to put in place the receiving socket with **etk** instruments shown in this manual.

The use of the implant requires a good mastery of the occlusion regulation, the management of implant axes during the preparation of the site, as well as a precise location of implants with regard to cusps and to occlusal forces. In a general way, any element of the treatment having an incidence on the distribution and the orientation of the masticatory constraints must be taken into account «not to overload» the implant.

To use the OBI abutment implant in fixed prosthesis, it is necessary to study the available restorative space before the implant placement, and the feasibility of the insertion of the implant in the prosthetic axis.

This implant tolerates very few alterations (see chapter about the pre-implant study).

When the OBI is used in removable prosthesis, the relining of the prosthesis is necessary to obtain a mucous support and not to concentrate the load on implants. A regular relining is necessary to assure the durability of the treatment.

PRE-IMPLANT STUDY

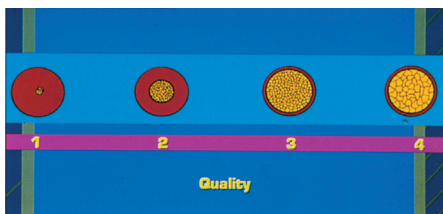
IMPLANT treatment feasibility

This study takes different elements into consideration

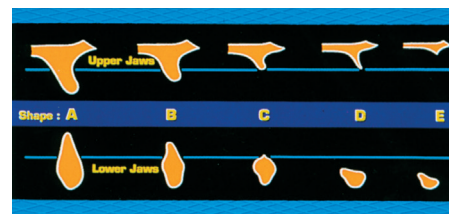
- 👉 A patient's questionnaire to reveal potential health/medications problems which could have a bearing on the treatment success, alcohol, use tobacco or drugs, general dental hygiene...
- 👉 An oral examination which will give details about the mouth opening, the line of the patient's smile (if it is a gingival smile), the coronary height and the volume of bone available, the type of occlusion...
- 👉 Biological tests (glycemy...)
- 👉 A complete X-Ray file showing the available bone's volumes
- 👉 Complete tests studies with the two dental arches in occlusion.
- 👉 An implant treatment cannot be started without a thorough cleaning of all the patient's infectious seats.
- 👉 If it is necessary, in case of reduced coronal height in fixed prosthesis, the ball can be removed but only once the osseo-integration of the implant ended, that is under a period from 3 to 6 months according to the arch.

- 👉 In spite of the one-piece design of the implant, the immediate loading is not compulsory: possibility of leaving a prosthesis out of occlusion or, in case of removable prosthesis, not connecting ball abutments with the overdenture during the time necessary for the osseointegration.
- However, because of the non-burying of the implant, and its small diameter, a precise analysis of the efforts applied to the implant and their distribution must be led to appreciate at best the feasibility of such a treatment.

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.

Guide for the IMPLANTS CHOICE

Available bone volume

In the mesio-distal plan

- Leave 3 mm between the thread of two implants.

In the labio-lingual palatal direction

- Leave, if possible, 1.5 to 2 mm of bone thickness around the labial, palatal & lingual surfaces.

Recommandations

- In the case of a removable prosthesis, the implants will have to be strictly parallel between them and situated perpendicularly to the occlusal plane.
- A regular relining of the prosthesis will allow to ensure the mucous support of the prosthesis and will so reduce the implants prompting.

Choice of the implant

- To stabilize a removable prosthesis, we recommend to use 4 implants, or at least 2. Select implants with a length of at least 11 mm if possible in the case of a stabilization on two implants.

Use OF THE SURGICAL TRANSPARENCIES

In order to guide the choice of the implant in terms of length and diameter, **etk** has developed surgical transparencies that show the dimensions of its different implants. Thereby, the implants are represented with 1:1, 1.3:1 and 1.7:1 magnifications (magnifications correspond to the usual magnifications of the different types of medical imaging systems: retroalveolar X-ray, X-ray dental panoramic and tomography analysis SCANORA, CBCT (Cone Beam)).

When the practitioner accurately knows the magnification of the pre-surgical X-ray, and if this magnification is 1:1, 1.3:1 or 1.7:1, by a simple superposition of the corresponding template (1:1 template for a 1:1 magnification, 1.3:1 template for a 1.3:1 magnification and 1.7:1 template for a 1.7:1 magnification), it is possible to determine which type of implant can be placed in the available bone volume.

When the practitioner does not know the magnification of the X-ray or to avoid any mistakes, he may place a reference object with known dimensions in the mouth of the patient when performing the X-ray examination in order to determine the associated magnification :

$$\text{Magnification} = \frac{\text{dimensions of the reference object measured on the radiograph}}{\text{real dimensions of the reference object}}$$

The real dimensions of the reference object shall be known to a minimum accuracy of $\pm 15\mu\text{m}$. The reference object shall be held in position using wax for example or by embedding the object in a partial impression. Care should be taken for the patient not to swallow the reference object. Use a safety thread if the geometry of the reference object allows it.

Then, if the calculated magnification is 1:1, 1.3:1 or 1.7:1, you may use the transparencies.

In all cases, if the magnification is not 1:1, 1.3:1 ou 1.7:1, it is not possible to use the transparencies provided by the **etk** but the bone volume may be determined thanks to proportionality calculation using the X-ray and the mesured magnification.

In this pre-implantation phase the practitioner must also design the coming prosthetic construction since implantology must be considered as a prosthetically driven project. Indeed, pre-prosthetic planning and surgical planning are closely linked and any change to one will have consequence on the other. It is during this phase that we may determine the number of implants, their diameters, their lengths, their locations and their orientations in order that we may proceed with the planned prosthetic construction.

SURGERY

Surgical KIT

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

- ▶ a calibration of the socket to obtain a good primary stability of the implant, main condition for the osteointegration.
- ▶ 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 imperviousness.
- ▶ The drilling axis should be controlled to avoid any angle between the prosthesis and the implant. Use the drill guide in the gingival cutter to respect a constant working axis.

- ▶ The instruments are sorted by their stage of use as shown by a marked on the kit. Numbers notify the main steps of each stage.

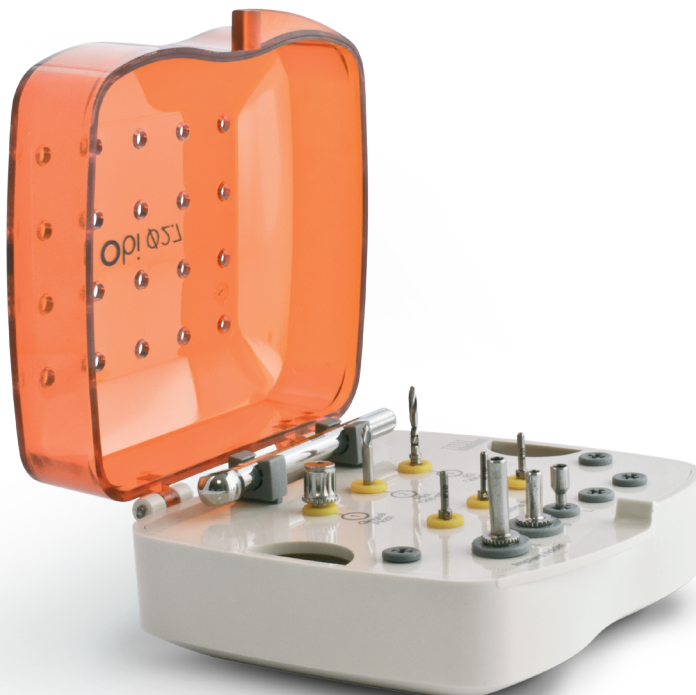
BE CAREFUL

It is necessary to choose the prosthetic parts before the implant placement in order to insert the implant at the right place.

WARNING

The minimum heating will be achieved with a good irrigation and with a good 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 to 15 uses.

Ref. OICK 27 XX 00



1. Gingival cutter

2. Point drill Ø 1.5- Ø 2.2

3. Drill Ø 2

4. Depth Gauge

5. Paralleling pins

- Click wrench

- Internal hexagonal screwdriver Ø 2.5 for the implant driving

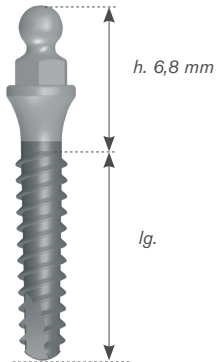
- Mandrel Extension

- Internal hexagonal mandrel Ø 2.5 for the implant driving (long and short)

Pictures for illustration purposes only

Mini implant range abutment/ball & ball OBI

Implants Ø 2.7 for removable prosthesis



Supplied on demand with an O'Ring attachment.

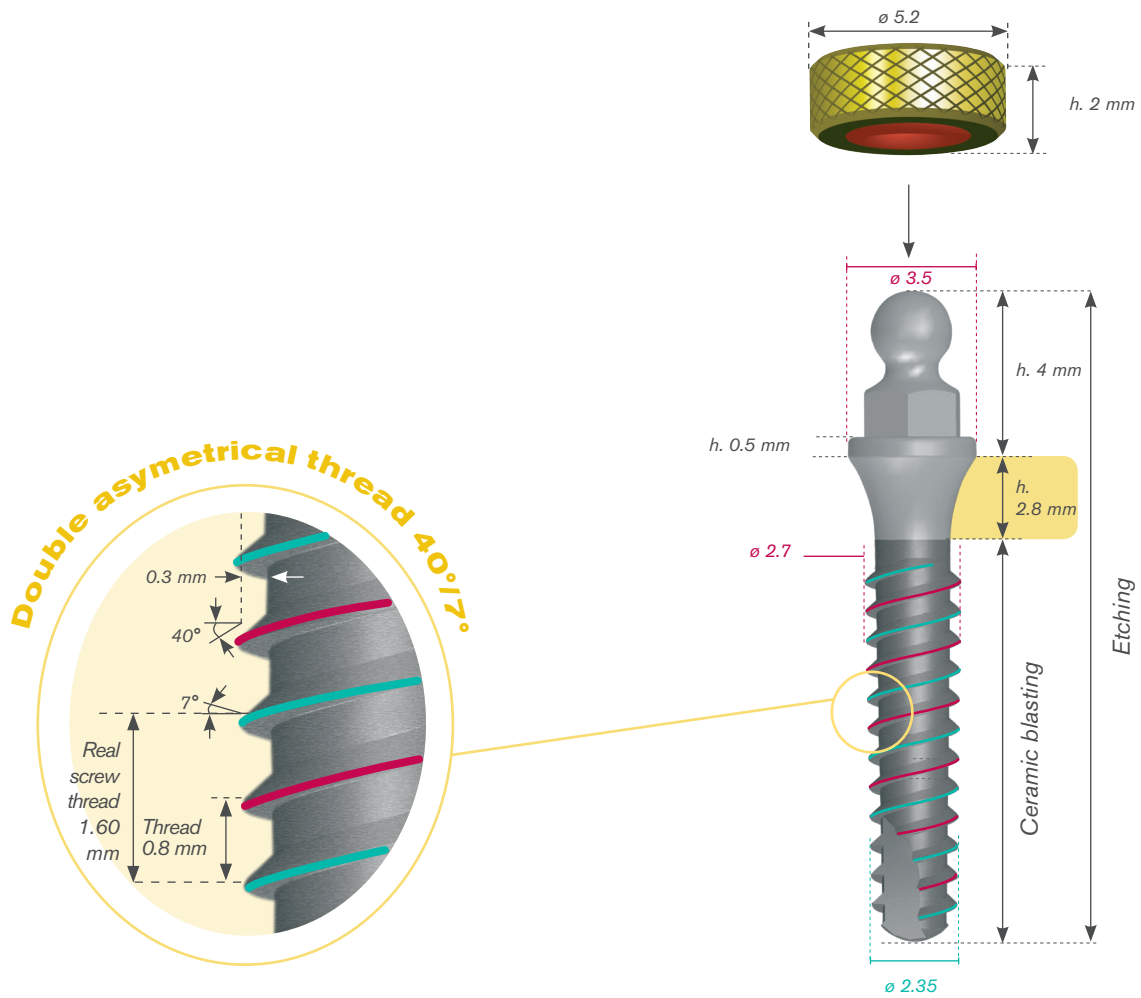
A reliable solution for OVERDENTURE STABILIZATION

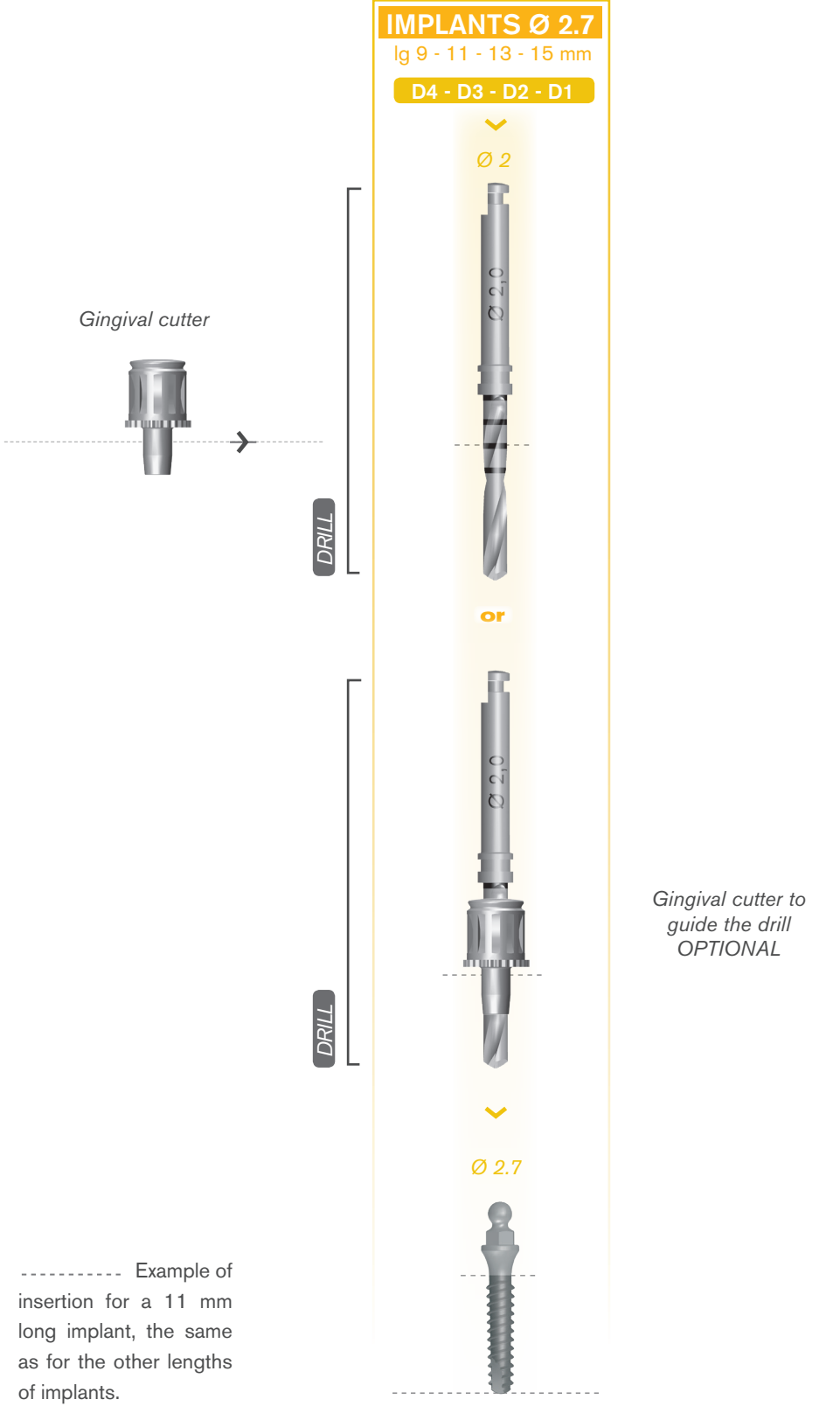
For thin edentulous crest, as an economical solution for some patients or for patients who do not accept implant treatment that requires several surgeries.

OBI implants can stabilize a complete denture on mucosal support.



Implant PICTURE





----- Example of insertion for a 11 mm long implant, the same as for the other lengths of implants.

1 Incision

According to the available osseous volume and to the practitioner experience, the incision will be practised.

Either with a blade of scalpal:

Make a crestal incision through the attached jaw, and then lift a flap.

Either with a gingival cutter supplied in the surgical kit:

Center the gingival cutter on the site to be implanted and press; remove the gingival piece in the center of the gingival cutter, put back the punch in place by checking its angular orientation because it will determine the drilling axis.

BE CAREFUL

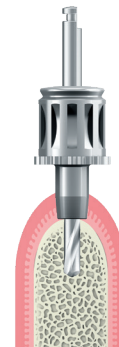
Save a minimum space around the implants according to the rules of implantology.
 In the labio-lingual / or palatal direction save 1.5 mm to 2 mm of bone.
 In the mesio-distal plan, save 2 mm between a natural tooth & the implant thread, or 3 mm between 2 implants threads.



2 Drill diameter 2 MM

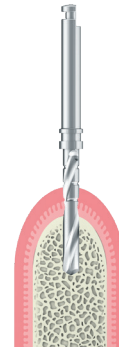
If the incision was carried by means of the gingival punch, the drill Ø 2 mm will be inserted into the central hole of the punch which will be used as a guide and will allow to stabilize the working axis of the drill at the time of the site shaping. It will then be correctly dimensioned. Check that the axis given by the mandrel of the drill is satisfactory before starting the motor.

Remove the punch after having made a first hole 3 or 4 mm deep.



The implants lengths 9, 11, 13 and 15 mm correspond to the threaded and sandblasted lengths, but do not include the collar which will be placed over the crest. (p.21)

Finalize the drilling up to the determined mark on the drill, under constant external irrigation of sodium chloride, and at a speed ranging from 1000 to 1200 rpm according to the quality of the bone. The progress of the drill has to be made without forcing. If that was the case, it indicates that osseous fragments do not manage to evacuate by going back up along the helix. A simple up-and-down movement will allow to obtain a fluids progress of the drill. Be careful to work according to a constant axis. This movement does not require reverse motion of the motor direction if it is made at the right time. If the drill is blocked, it can be removed in «reverse» mode.



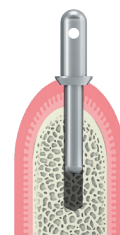
The depth of use of the drill is going to determine the implant compression in the bone. The drill Ø 2 mm is provided with 4 marks at 9, 11, 13 and 15 mm. These lengths are «point of drill included».

The peri-implant bone in the apical area of the implant is generally not so hard; the primary stability of the implant can be improved in this area by reducing the depth of drilling with regard to the total length of the implant. The implant is slightly conical and has self-tapping vents, so it can progress in this area.

3 Control OF THE SOCKET AXIS

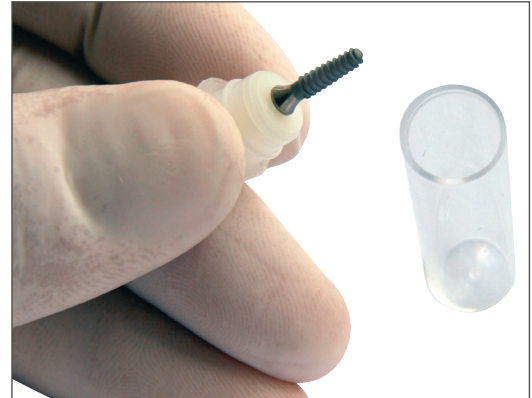
Insert the thinnest side of the parallelism gauge in the implant socket to evaluate the emergence axis of the implant and to guide the second drilling if necessary.

The top part of the gauge is necked to prefigure the implant neck (prosthetic support), and to save the necessary space between two implants.

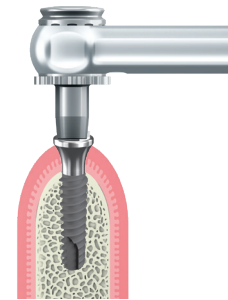


4 Implant INSERTION

The implant can be positioned manually or with the contra-angle. This procedure must be done with the greatest care so that the implant does not come in contact with any non sterile element before insertion in the bone site. The cap of the implant tube can be used as an implant carrier. Take the implant to the implant bed, and insert it at the entrance of the well. Screw some turns of threading. Remove the cap and finish the screwing with the click-wrench provided with the internal hexagonal key.



For a good positioning in with the contra-angle, we recommend a speed of 15 to 25 rpm to control the descent of the implant. The positioning with the contra-angle allows to measure the insertion torque of the implant and to evaluate its primary stability. We recommend to set the implant at minimum 30 N.cm for a delayed loading, and higher than 40 N.cm for early or immediate loading.



It is recommended to check the primary stability of the implant at the end of the screwing by trying to move it. If the implant is loose, its primary stability is insufficient and will compromise the osseointegration; it is better to remove it and to use an implant with a greater diameter if the bone volume allows it.

5 Osseointegration

The conventional period to get a good osseointegration is 3 months at the mandibular.

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

Studies and scientific datas indicate that at the mandibular a prosthesis stabilized on 4 implants is possible.

In case of failure

To remove an implant, use a trephine with a greater diameter than the implant and remove the obtained bone cylinder.

The site can possibly be re-implanted, if the patient is fit to receive a new implant, with an implant of greater diameter, in the case that the placement of this implant occurs at the same time*.

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

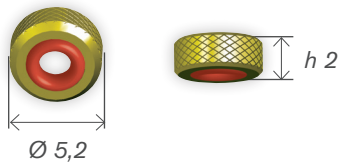
* It is important that the reasons of the failure should be analyzed before placing a new implant.
 ** The doctor decides if it is necessary to use some bone to fill in the socket.

PROSTHESIS

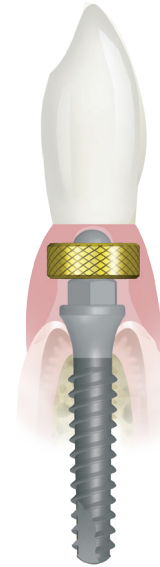
Overdenture STABILIZATION

BE CAREFUL

For the mandible only. Be careful to have a mucous support of the prosthesis not to concentrate all the support and retention on the implants.



O'ring attachment
Ref. UPA FOR 52
with retaining ring 60 shores



A If the removable prosthesis of the patient is re-used

The inner side of the removable prosthesis is hollowed out to place the female parts of all implant

- 1.A** After the implant head is protected with a fine paper or insulating material, the female part is snapped on the implant head; some resin is introduced into the prosthesis, which is then seating in mouth by adjusting the occlusion and the positioning. The resin will get harder by autopolymerization.
- 2.A** After the hardening of the resin around the female attachments, the prosthesis is ready.
- 3.A** Reline the prosthesis to adjust the mucous support.

B If the prosthesis is made in the laboratory

- 1.B** Make the impression on the titanium implants.
- 2.B** Withdraw the impression.
- 3.B** Insert the implant analogs in the impression.
- 4.B** Cast the model.
- 5.B** Snap the female parts.
- 6.B** The prosthesis is made by means of teeth in resin positioned in the wax according to the same process as a complete prosthesis in exclusively mucous support.
- 7.B** The prosthesis is placed on the articulator to check the occlusion and the positioning of teeth; adjustments if necessary.
- 8.B** Put in the casting flask.
- 9.B** Try the prosthesis on the model.
- 10.B** Snap the prosthesis on the implants in the mouth.

STUDIES & PUBLICATIONS

👉 **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 - GUY HURÉ** - Encyclopédie médico-chirurgicale Odontologie 9-1989 23345 A¹⁰

👉 **Thérapeutique implantologique Endo-osseuse originale - Le site Tubero-pterygoïdien - GUY HURÉ** - Les cahiers de prothèse n°67 - Septembre 1989

👉 **A propos de l'état de surface des implants en titane pur - Docteur GUY HURÉ** - Implantodontie - 1994 - N°14/15

👉 **Comment choisir un anesthésique en odontostomatologie - 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'articaine associées à une analgésie - Intraveineuse en chirurgie buccale chez les malades à risque** - Par B. Lefevre, J. 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**
Franck Renouard

