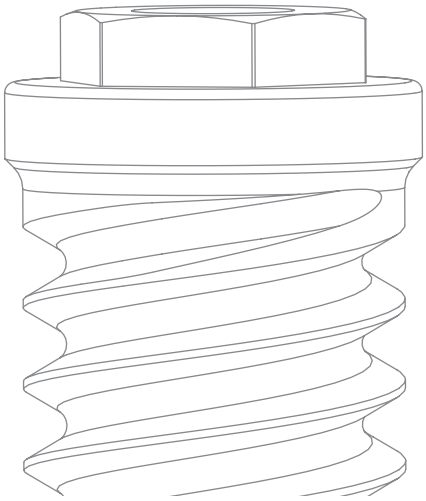
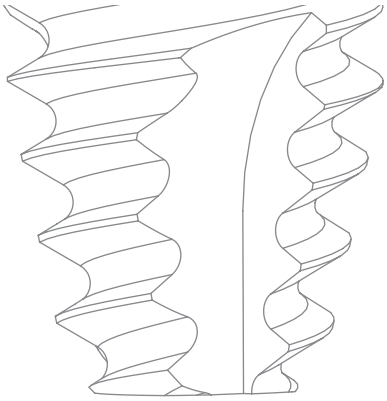


GMI® PHOENIX

implant system



Surgical procedures guide

ABOUT THIS MANUAL

This surgical procedures guide or surgical manual for the **GMI® phoenix** implant system is designed solely to provide instructions for using **GMI® phoenix** products, and is not intended to describe diagnosis methods or procedures, treatment planning or the location of the implants, nor does it replace clinical training or clinical judgement about the needs of each patient. **GMI®** recommends appropriate and specific training as a prerequisite for the placement of implants and the associated treatment.

The methods illustrated and described in this manual reflect an ideal patient with the bone and soft tissue required for the placement of an implant. We do not intent to cover the wide range of adverse conditions that may negatively affect the success of the surgery or rehabilitation. **The experience and judgement of the clinician in relation to any particular case must always be above the recommendations made in this or any other GMI® manual.**

Rx only - Caution: Federal (USA) law restricts these devices to sale by, or on the order, of a dentist or physician.

TABLE OF CONTENTS

DESCRIPTION OF THE IMPLANT SYSTEM

INDICATIONS

GMI® Phoenix Dental Implant System is intended to be used for surgical placement in upper or lower jaw to provide a support for prosthetic devices such as artificial teeth, in order to restore the patient's chewing function. These products should only be used by trained professionals.

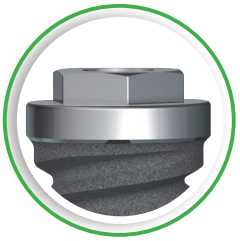
KEY FEATURES

HIGH PRIMARY STABILITY

The thread of the implant body enables obtaining a good primary stability in all bone densities.

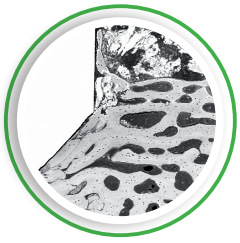
UNIVERSAL HEXAGONAL CONNECTION

Universal external hexagon of RP Hex 2,70 x 0,70 mm platform. High precision machining to minimize rotational micromovement.



EXCELLENT BIOLOGICAL RESPONSE

Implant made of pure grade 4 titanium with an exclusive ADS surface treatment that generates an excellent biological response promoting osseointegration of the implant even in the most complicated cases.



IMPLANT RANGE

The **GMI® phoenix** implant range consists of implants available in 5 different diameters and different lengths to suit all clinical situations:

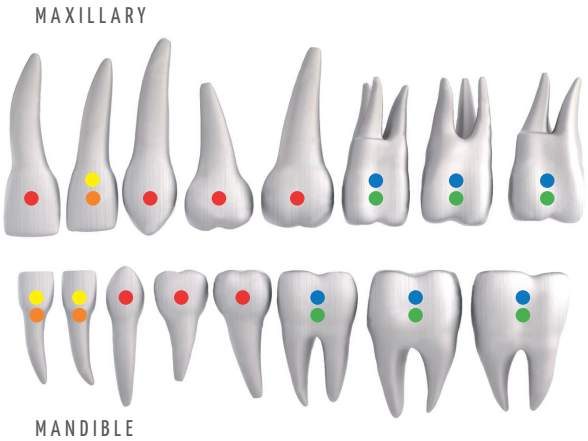
Ø EXT. THREAD	Ø3.30 mm	Ø3.30 mm	Ø3.75 mm	Ø4.00 mm	Ø5.00 mm	Ø6.00 mm
COLOUR	●	●	●	●	●	●
Ø PLATFORMS	Ø3.30 mm	Ø4.10 mm	Ø4.10 mm	Ø4.10 mm	Ø5.10 mm	Ø6.00 mm
EXT. HEXAGON	b/f-2.40 mm	b/f-2.70 mm	b/f-2.70 mm	b/f-2.70 mm	b/f-2.70 mm	b/f-3.40 mm
LENGTHS	8 to 15 mm	8 to 17 mm	8 to 17 mm	8 to 17 mm	6.5 to 13 mm	6.5 to 10 mm

USAGE RECOMMENDATIONS

Before starting any type of surgical procedure with **GMI®** implants follow the recommendations below:

- Plan the treatment using radiological templates or digital planning.
- Observe the distances between the implant and tooth adjacent to and between adjacent implants.
- Read the instructions for use at www.gmidental.com/ifu.
- Become familiar with all instrumental parts and their usage.
- Read the specific drilling sequences for each implant diameter.
- Clean and properly sterilize surgical kit following the instructions.

GMI® phoenix implants have been designed to be used as a unitary restoration according to the following occlusal diagram:



●● Ø3.30-Ø3.75 mm

- Incisors
  (Except central maxillary)

● Ø4.00 mm

- Canines
- Premolars
- Central maxillary incisors

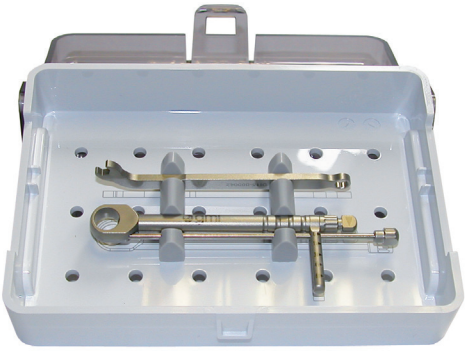
●● Ø5.00-Ø6.00 mm

- Molars

IMPLANT SYSTEM LABELLING DESCRIPTION

In the chart are detailed all the symbols that appear on the implant system labelling and packaging and their corresponding description:

GMI® PHOENIX SURGICAL KIT



The **GMI® phoenix** surgical kit consists of a box of autoclavable technical plastic which includes all the necessary components for preparing the bone bed and placing the implant.

DENTAL DRILLS

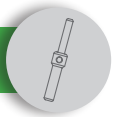
• **Lanced drill:** Enables marking the beginning of the osteotomy and performing the initial drilling of the cortical plate.

• **Pilot drill:** Enables starting the osteotomy by performing a drilling of Ø2.00 mm to the desired depth. To control the depth the high contrast depth markings can be used or the GMI® drill stops.

• **Guide drill:** Enables widening the osteotomy from Ø2.00 mm to Ø2.70 concentrically using the built-in guide.

• **Final drill:** Enables progressively widening the osteotomy to the final diameter and depth required for implant placement. To control the depth the high contrast depth markings can be used or the GMI® drill stops.

PARALLELING PINS

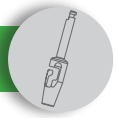


Once inserted into the bone bed, it enables checking the parallelism between the preparation and other adjacent structures or implants. It can be used on both sides depending on the diameter of the drilling: on one side it measures Ø2.00 mm and on the other side Ø2.80 mm.

DEPTH GAUGE

Once inserted into the osteotomy it enables checking the depth of the preparation to adapt it to the length of the implant to be placed. There are two models with different diameters: Ø2.80 mm and Ø3.50 mm. The marks of the implant lengths are included (L6.5/L8/L10/L11.5/L13/L15/L17).

TIP EXTENDER



In cases where it is necessary it increases the length of the components with HP connections by 15 mm.

HEX-1.20 HEXAGONAL WRENCHES

Once introduced in the hexagon socket part, it enables screwing and loosening the healing abutments and the clinical screws. They are designed both for manual use as well as coupled to the TI ratchet wrench. They are available in long (28 mm) and short (21 mm) versions.

CARRIER WRENCHES

Once inserted correctly in the carrier hexagon it enables removing the implant from the container, putting it into the mouth, starting the thread manually in the bone bed and carrying out the final insertion with the TI ratchet wrench. There is also a version with HP connection.

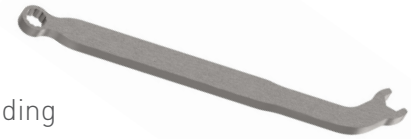
COVER SCREW WRENCHES

Once inserted correctly in the cover screw hexagon it enables removing them from the primary plug, putting them into the mouth and threading them to the implant. They are available in HEX-0.80 version for ø3.30 mm implants with ø3.30 mm platform, and HEX-1.20 for the rest of the range.

TI RATCHET WRENCH

Ratchet wrench with torque indicator (TI) allows controlling the insertion torque when screwing the implant during the surgical procedure, and accurately applying torque on the attachments during the prosthetic phase. See instructions for reference.

MANUAL WRENCH 45º



Once coupled to the external hexagon of the carrier it enables avoiding the rotation of the implant when the clinical screw is loosened.

OPTIONAL SURGICAL INSTRUMENTS

This section describes the optional surgical instruments used only in specific cases and that are not part of the **GMI® phoenix** surgical kit.

GINGIVAL PUNCH

Enables making circular incisions directly into the soft tissue, avoiding having to do the flap technique to discover the implant bone bed. They are available in cut diameters of Ø5.00 and Ø6.00 mm.

THREAD FORMERS

Enables working the implant thread in the bone bed once the preparation is completed to facilitate threading the implants in type I and type II dense bone type. They are available separately for each implant diameter and in a kit that includes all the **GMI® phoenix** system thread taps.

HP ADAPTOR WRENCH

Adapter that allows using all the wrenches with a HP connection (hand-piece) manually or coupled to the TI ratchet wrench.

DEPTH STOPS FOR DRILLS

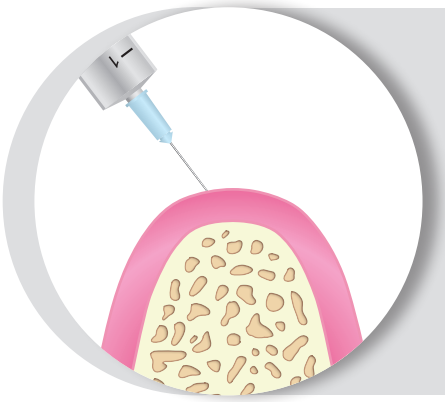
For controlling in a simple, precise and safe way the drilling depth of the bone bed depending on the length of the implant to be placed. They are available in three diameters depending on the diameter of the drill to be used: L1 (for drilling from Ø2.0 mm to Ø3.0 mm) L2 (for drilling from Ø3.2 mm to Ø4.3 mm) and L3 (for drilling between Ø4.5 mm and Ø5.4 mm) and for implant lengths between 6.5 mm and 15 mm. They are available separately or in a kit that includes all the stops.

IMPLANT EXTRACTOR

Once introduced into the internal thread of the implant, it enables removing a failed implant from the bone bed, preventing the use of trephines and thus preserving a greater amount of bone. They are designed to be used manually with the TI torque wrench.

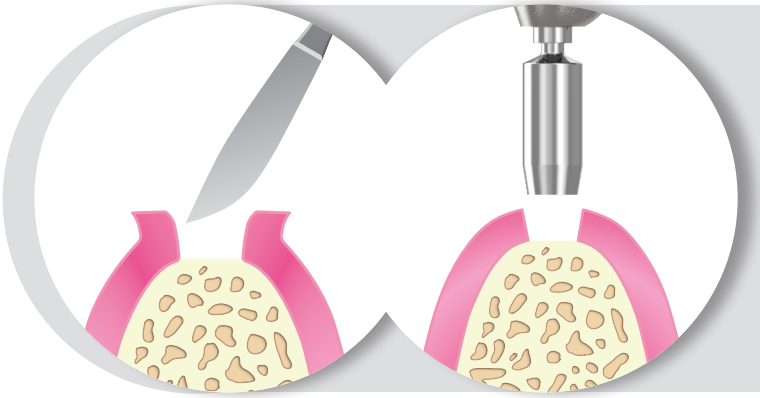
SURGICAL PROTOCOL (step 1)

BONE BED DRILLING



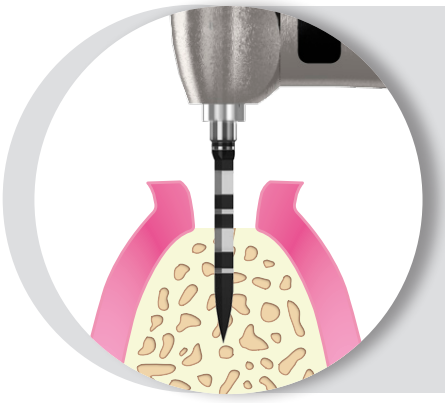
1. Anaesthetize

Apply infiltrative anaesthesia in soft tissues following standard clinical procedures.



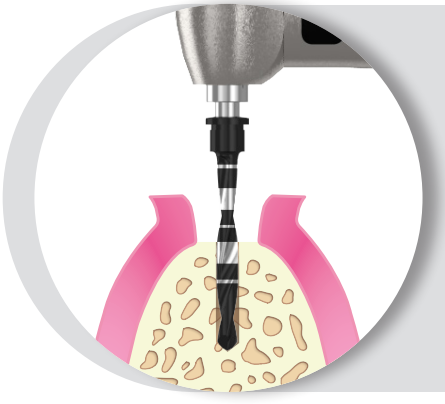
2. Perform soft tissue incision

Identify the anatomical area to respect and uncover the bone in the implant placement by making a crestal incision with a scalpel if use the flap technique, or using a manual gingival punch for flapless technique (Ref. KYL0F0024 or KYL0F0082) or with a HP connection (Ref. KYL0C0074 or KYL0C0075).



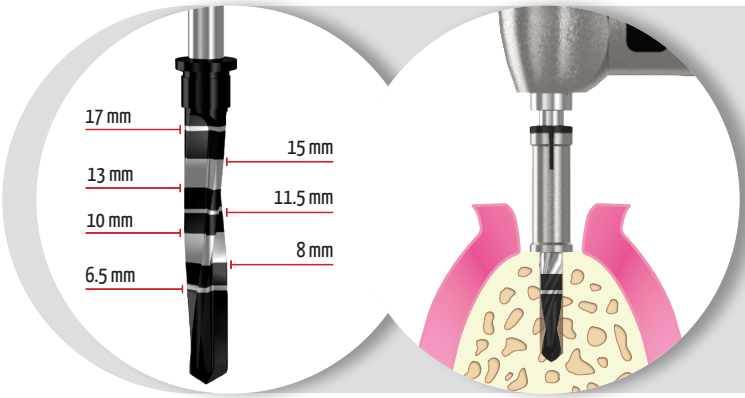
3. Mark osteotomy beginning

Set the engine speed between 1200-1500 rpm, depending on bone density, and use the lance-shaped drill (Ref. KYF0C1225) to mark the bone and start the osteotomy. Use plenty of external cooling with saline solution at a low temperature.



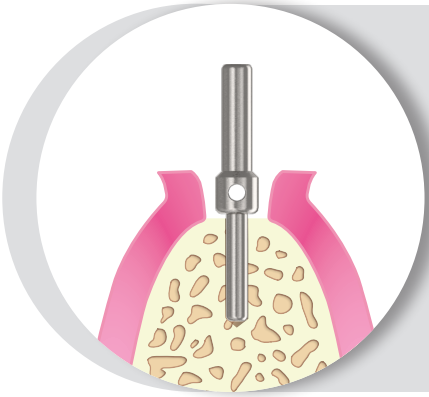
4(a). Perform initial drilling

Set the engine speed between 900-1200 rpm, depending on the bone density, and use the Ø2.00 mm pilot drill (Ref. KYF0C2221) to determine the angle and depth of the osteotomy. Use plenty of external cooling with saline solution at a low temperature.



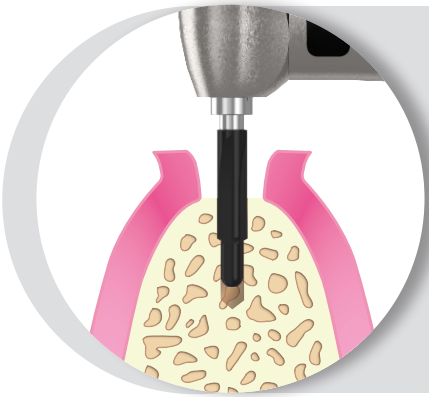
4(b). Drill depth control

To control the depth of the osteotomy use the high contrast visual markers on the drill or the appropriate stop. For the reference see the **GMI®** stop instructions for use.



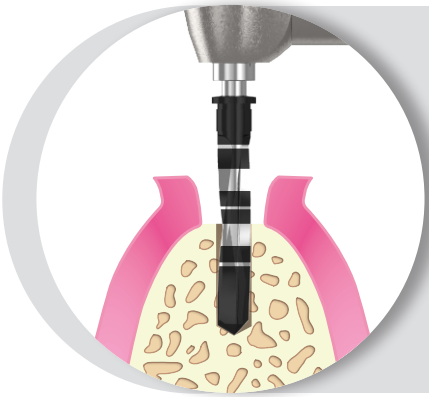
5. Check position and parallelism

Insert the Ø2.00 mm diameter paralleling pin on the side (Ref. KYL0C0078) to check the position and angle of the osteotomy.



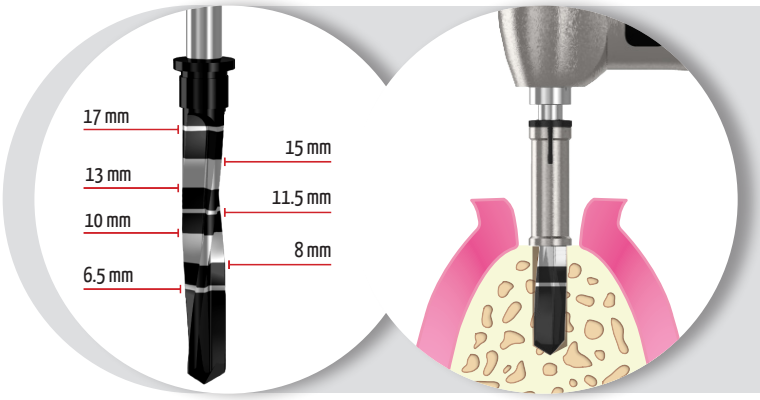
6. Perform guide drilling

Set the engine speed between 800-900 rpm, depending on bone density, and use the guide drill (Ref. KYF0C3227) to carry out a concentric drilling that will help to centre the following drilling in the sequence. Use plenty of external cooling with saline solution at a low temperature.



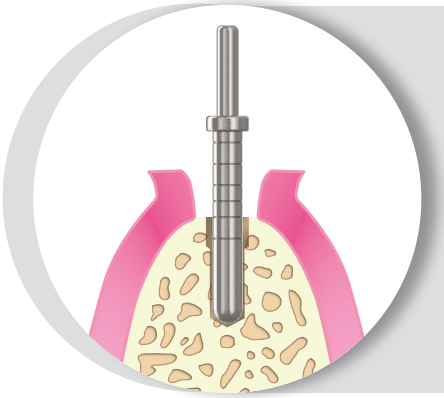
7(a). Carry out the widening of the osteotomy

Set the engine speed between 400 and 700 rpm, depending on the bone density, and use Ø2.80 to Ø5.10 mm drills (Ref. KYC0C01XX) to progressively widen the osteotomy. Use the appropriate drilling sequence for each implant diameter (see next section for reference). Use plenty of external cooling with saline solution at a low temperature.



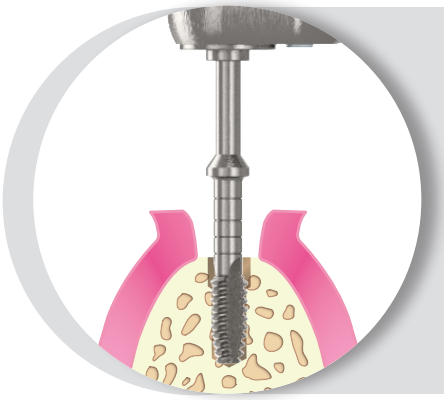
7(b). Drill depth control

To control the depth of the osteotomy use the high contrast visual markers on the drill or the appropriate stop. For the reference see the **GMI®** stop instructions for use.



8. Check depth

Insert the Ø2.80 mm depth gauge (Ref. KYL0C0094) or Ø3.50 mm (Ref. KYL0C0095) to check the depth of the osteotomy to make the final drilling for each implant diameter. Increase the depth of the osteotomy in case of not having the necessary depth.



9. Pass forming thread (OPTIONAL)

For dense bones (Type I and Type II) use the thread formers (Ref. KYM0C00XX) to form the thread of the implant in the bone and to avoid having to apply an excessively high insertion torque during the implant insertion.

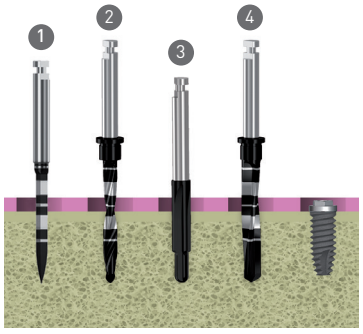
DRILLING SEQUENCES

The **GMI® phoenix** implant system drilling sequences and the recommended conditions for use are as follows:

- **Lance-shaped drill**: 1200-1500 rpm.
- **Pilot drill**: 900-1200 rpm.
- **Guide drill**: 800 rpm.
- **Final drilling**:
  - Ø2.80 mm ----------→ 500-700 rpm.
  - Ø3.00 – Ø3.50 mm ----------→ 400-700 rpm.
  - Ø4.00 - Ø5.10 mm ----------→ 400-600 rpm.

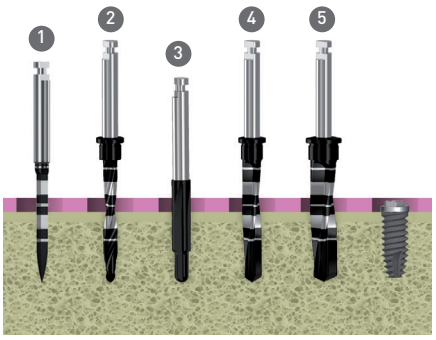
PHOENIX IMPLANT SEQUENCE Ø3.30 mm

1- Lance-shaped drill (KYF0C1225)
2- Pilot drill (KYF0C2221)
3- Guide drill (KYF0C3227)
4- Final drill Ø2.80 mm (KYF0C0128)
5- Thread former Ø3.30 mm (KYM0C0009)*



PHOENIX IMPLANT SEQUENCE Ø3.75 mm

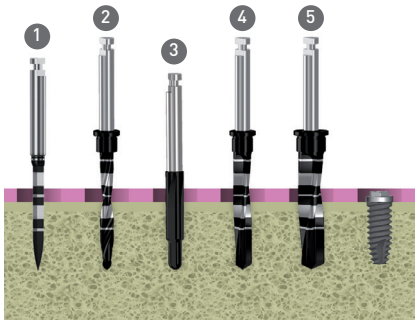
1- Lance-shaped drill (KYF0C1225)
2- Pilot drill (KYF0C2221)
3- Guide drill (KYF0C3227)
4- Final drill Ø2,80 mm (KYF0C0128)
5- Final drill Ø3,25 mm (KYF0C0132)
7- Thread former Ø3.75 mm (KYM0C0010)*



* Optional for dense bones type I and type II.

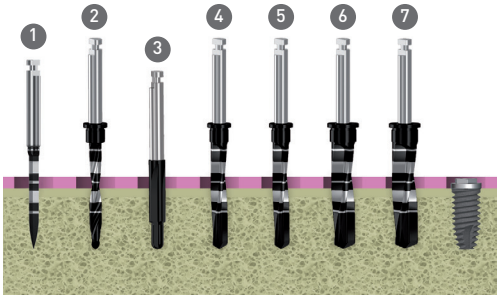
PHOENIX IMPLANT SEQUENCE Ø4.00 mm

1- **Lance-shaped drill** (KYF0C1225)
2- **Pilot drill** (KYF0C2221)
3- **Guide drill** (KYF0C3227)
4- **Final drill Ø2.80 mm** (KYF0C0128)
5- **Final drill Ø3.50 mm** (KYF0C0135)
6- **Thread former Ø4.00 mm** (KYM0C0011)*



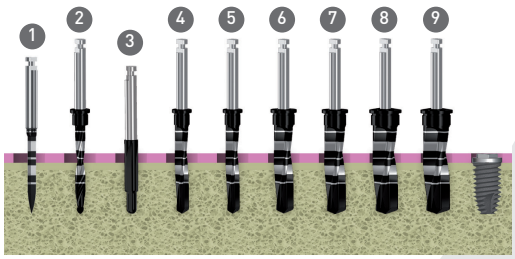
PHOENIX IMPLANT SEQUENCE Ø5.00 mm

1- **Lance-shaped drill** (KYF0C1225)
2- **Pilot drill** (KYF0C2221)
3- **Guide drill** (KYF0C3227)
4- **Final drill Ø2.80 mm** (KYF0C0128)
5- **Final drill Ø3.00 mm** (KYF0C0130)
6- **Final drill Ø3.50 mm** (KYF0C0135)
7- **Final drill Ø4.25 mm** (KYF0C0143)
8- **Thread former Ø5.00 mm** (KYM0C0012)*



PHOENIX IMPLANT SEQUENCE Ø6.00 mm

1- **Lance-shaped drill** (KYF0C1225)
2- **Pilot drill** (KYF0C2221)
3- **Guide drill** (KYF0C3227)
4- **Final drill Ø2.80 mm** (KYF0C0128)
5- **Final drill Ø3.00 mm** (KYF0C0130)
6- **Final drill Ø3.50 mm** (KYF0C0135)
7- **Final drill Ø4.25 mm** (KYF0C0143)
8- **Final drill Ø5.10 mm** (KYF0C0151)
9- **Final drill Ø5.40 mm** (KYF0C0154)
10- **Thread former Ø6.00 mm** (KYM0C0015)*



* Optional for dense bones type I and type II.

NOTE: **GMI®**'s recommended process cannot replace the judgement and experience of the surgeon.

IMPLANT INSERTION

1. Initial check

Ensure that the diameter and length indicator sticker, located at the bottom of the outer case, matches the diameter and length of the implant to be placed. Check the expiry date that appears in the front label is later than the date of use.

2. Open outer package

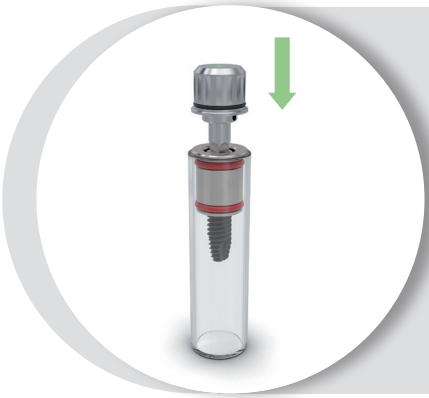
Open the tab on the box and remove the secondary packaging and adhesive labels identifying the product. Check the integrity of the secondary packaging. If some type of product manipulation is noticed please discard it.

3. Open the secondary container and remove the primary container

Check the security seal on the secondary container and discard the implant if there are signs of it having been tampered. Turn the cap anti-clockwise to break the seal. Remove the primary container and avoid hitting it against a hard surface.

4. Open primary packaging cap

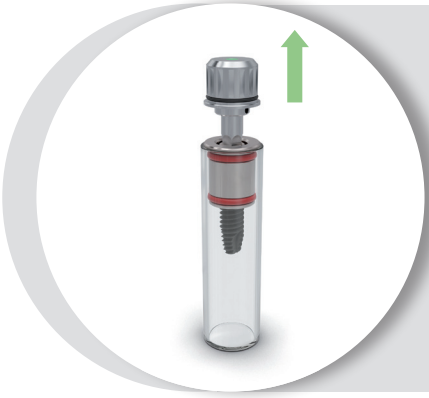
Hold the primary container vertically with the cap upwards and open the cap with a lateral movement. Store the primary cap vertically for the last phase of surgery because it contains the sealing cap inside.



5. Insert the key into the implant

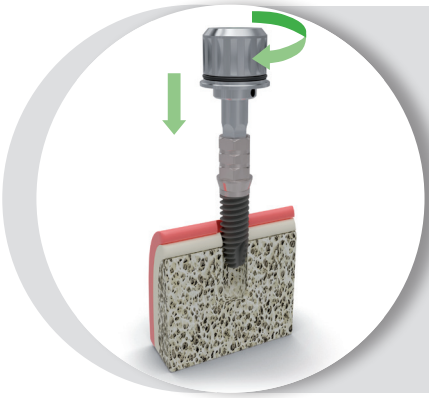
Keeping the container upright, insert the **Phoenix** short or long wrench (Ref. KYL0F0123 or KYL0F0124) inside the carrier, taking into account correctly orienting the hex wrench and carrier until it stops.

Important: Ensure that the wrench is fully inserted into the carrier before removing it from the internal support.



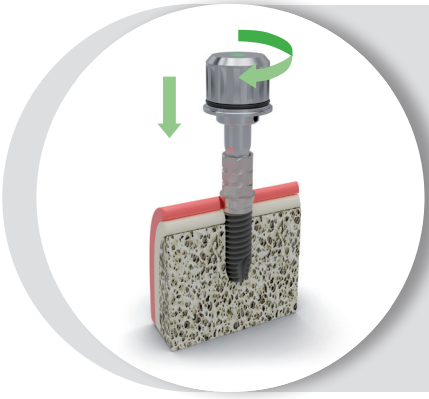
6. Extract set from the primary container

Once the wrench is properly inserted in the carrier gently remove the entire set as vertically as possible, preventing where possible the implant from rubbing the titanium support.



7. Implant insertion

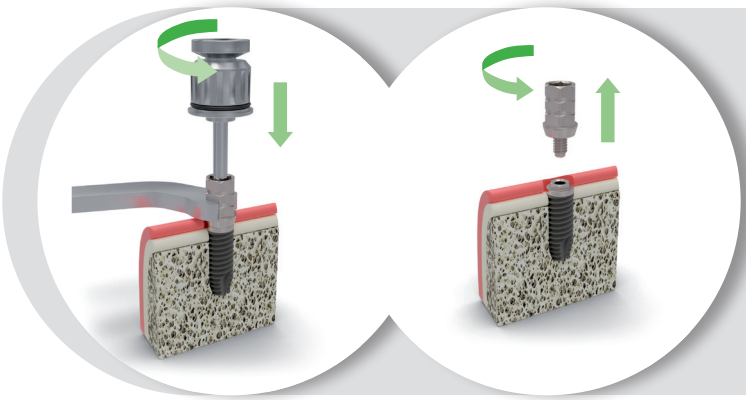
Perform the initial implant insertion manually in the bone bed prepared in the previous step.



8. Finish inserting the implant

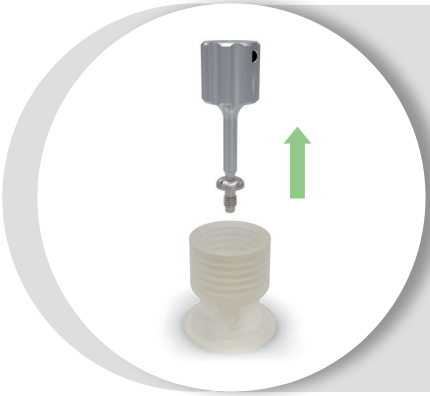
Finish inserting the implant with the TI torque ratchet wrench until it is placed on the crestal level, applying a torque of **35 N•cm**. With the aid of the hexagon faces remove from the carrier, guide one side of the hexagon of the implant towards the face.

Important: Do not exceed 60 N•cm during the insertion of the implant to prevent the connection from deforming.



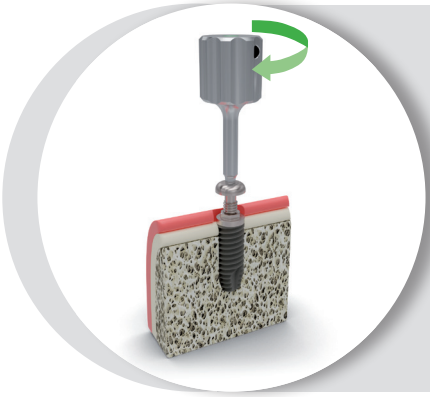
9. Dismount the carrier

Unscrew the clinic screw and dismount the implant carrier by turning slightly counter-clockwise if necessary. Use the flat wrench (Ref. KYL0C0093) to avoid turning the set while the clinical screw is loosened.



10. Extract cover screw

Insert the HEX-1.20 mm wrench (Ref. KYL0C0011) or the HEX-0.80 mm wrench (Ref. KYL0C0092) in the cover screw hexagon and lightly press down. Slightly turn anti-clockwise to remove the wrench-cap from the inner housing of the primary cap.



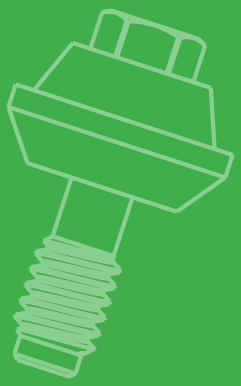
11. Place the cover screw in the implant

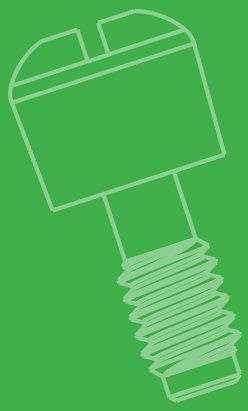
Ensure that the connection is free of bone debris or soft tissue. Using the appropriate wrench (HEX-1.20 or HEX-0.80) manually thread the cover screw to the implant, applying a torque of **15 N•cm**.

12. Suture the incision

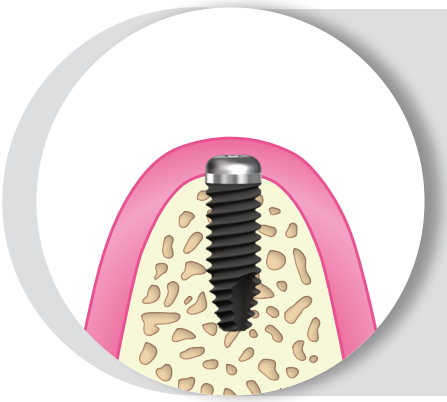
Verify that the implant is in the correct position and that the cover screw sits perfectly on the connection. Suture the incision according to standard clinical procedures. Take a radiograph to verify the proper placement of the implant and attach it to the files.

SURGICAL PROTOCOL (step 2)



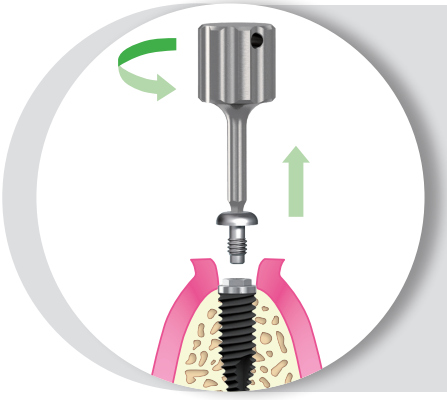


HEALING ABUTMENTS



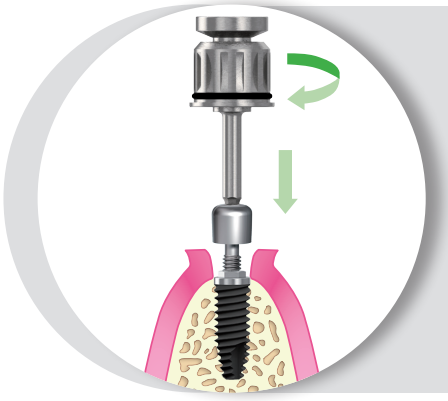
1. Uncover cover screw

Once the implant obtains osseointegration, in the case of a delayed loading protocol, proceed to the second stage of surgery making an incision to uncover cover screw.



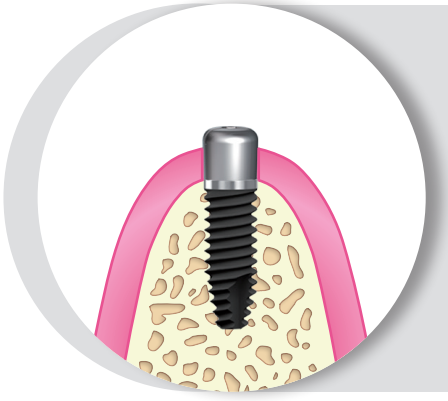
2. Remove the cover screw

Manually unscrew the cover screw with the HEX-1.20 mm wrench (Ref. KYL0C0011) or HEX-0.80 (Ref. KYL0C0092) and extract it from the implant.
Ensure that the implant connection is free of bone or soft tissue.



3. Select and thread the healing abutment

Select the height and diameter of the healing abutment according to the emergency profile desired and the thickness of the existing soft tissues. Screw the selected abutment to the implant manually with the HEX-1.20 mm wrench (Ref. KYL0F0128) applying a torque of **15 N•cm**.



4. Check height and suture

Ensure that the healing abutment is properly placed in the implant, and it stands between 1 and 1.5 mm above the level of the gum.
Suture the soft tissue around the abutment and wait until the healing phase has finished.

MULTI-ESTHETIC HEALING ABUTMENTS

FUNCTION

Healing abutments for multi-esthetic abutments are responsible for protecting the parts connecting the abutments and preventing irritation to soft tissues after surgery, when an immediate restoration will not be performed.

NECESSARY MATERIAL

Straight ME abut.

Healing abutment ME

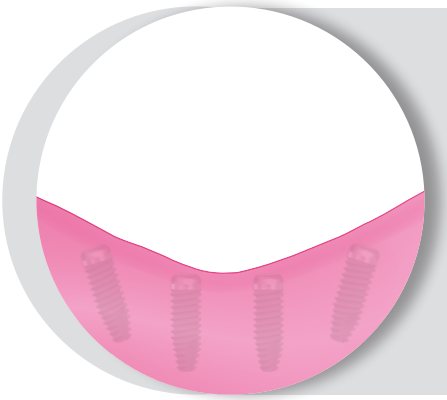
Angled ME abut.

MEA wrenches HEX-2,00 - HEX-2,50

Angled MEA wrench HEX-1,20

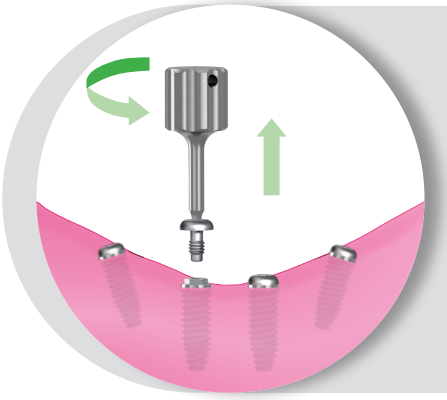
Manual wrench HEX-1,20

PROCEDURE



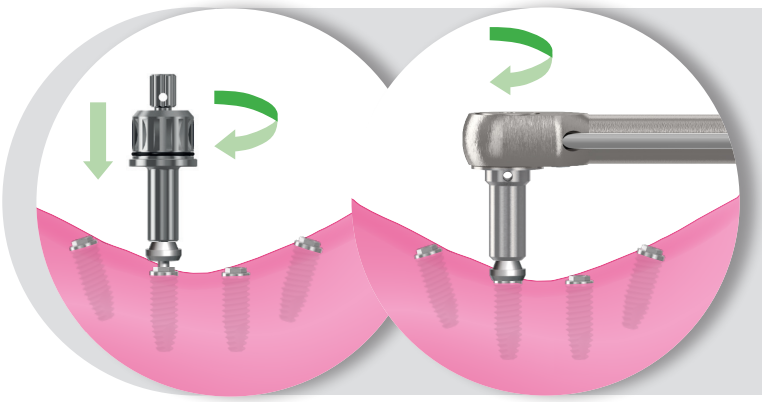
1. Uncover cover screws

Once the implant obtains osteointegration, in the case of a delayed loading protocol, proceed to the second stage of surgery making an incision to uncover the cover screws.



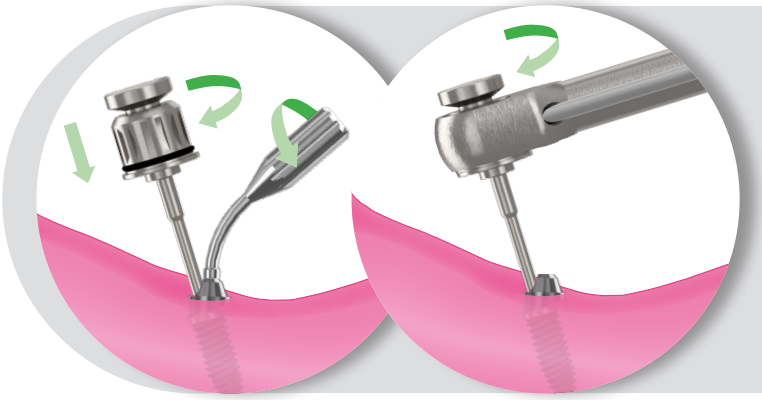
2. Remove cover screws

Manually unscrew the cover screws from the implant with the HEX-1.20 mm wrench (Ref. KYL0C0011) or HEX-0.80 (Ref. KYL0C0092) and extract them from the implants.
Ensure that the implant connections are free of bone or soft tissue.



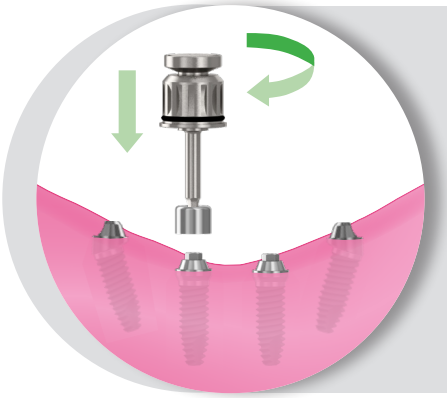
3. Select and thread the straight ME abutments

Select the emergency height and diameter of the straight ME abutments based on the implant platform and the existing soft tissue thickness. Screw the selected abutments to the implants manually with the ME abutment wrench (Ref. KYL0F0180 or KYL0F0181) and end the tightening with the wrench attached to the PI torque wrench using a torque of **30 N•cm**.



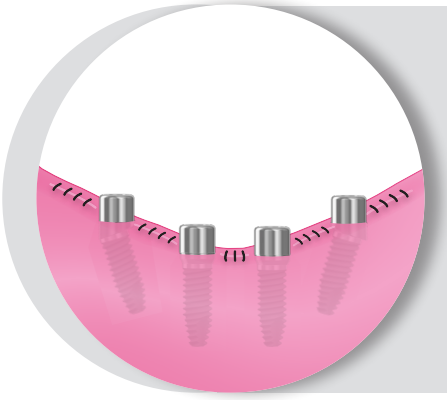
4. Select and thread the angled ME abutments

Select the diameter and angle of the ME abutments depending on the angle of the implant platform. Position the abutment and screw the angled ME abutment to the implant manually with the wrench for the inclined ME abutment (Ref. KYL0F0130). Unscrew the abutment guide and finish the tightening with the wrench attached to the PI torque wrench using a torque of **30 N•cm**.



5. Select and thread ME healing abutments

Ensure that the platform and the cone of the multi-esthetic abutments are free of bone and soft tissue. Select the healing abutment according to the ME abutment platform and screw it to the implant manually with the HEX-1.20 mm wrench (Ref. KYL0F0128) applying a torque of **15 N•cm**.



6. Check and suture

Ensure that all the healing abutments are seated correctly.
Suture the soft tissue around them.

NOTES

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