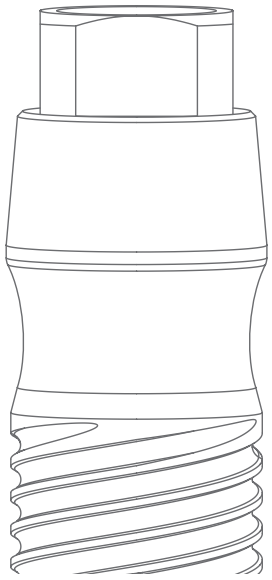
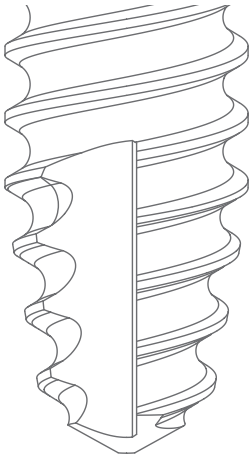


GMI® MONOLITH

implant system



Surgical procedures guide

ABOUT THIS MANUAL

This surgical procedures guide or surgical manual for the **GMI® monolith** implant system is designed solely to provide instructions for using **GMI® monolith** 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® monolith dental implants system model is intended to be used through one-stage surgery in upper or lower jaw in cases of total or partial edentulism or in cases of loss of isolated teeth (single restoration).

The implant system allows performing the following restorations:

- Unitary cemented restorations of mandibullar or maxillar lateral incisive. For these cases, h=2 mm implant must be used.
- Multiple cemented restorations of small bridges with splinted implants in incisive. For these cases, h=2 mm must be used.
- Stabilization of implant-retained and tissue-supported overdentures. For these cases, h=2 mm and h=4 mm implants can be used.

KEY FEATURES

CRESTAL BONE PRESERVATION

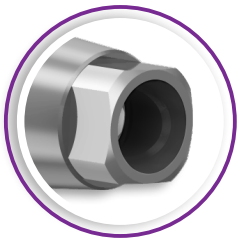
The treatment of the entire outer surface of the implant with its subcrestal placement and cortical micro-threading increases the surface of bone-implant contact, thus improving load distribution and reducing crestal bone resorption.

HIGH PRIMARY STABILITY

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

STABLE AND ACCURATE CONNECTION

Dual conical connection: external and internal connection. The external cone allows to make single or multiple cemented restorations. The internal cone allows the stabilization of implanto-retained overdentures.
Self-locking cones that create a rigid connection and a stable biological seal.



EXCELLENT BIOLOGICAL RESPONSE

Implant made of pure grade IV 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® monolith** consists of Ø3.00 diameter implants with different lenghts (L) and two gingival collar heights (h) to suit all clinical situations:

COLOUR	Ø BODY	Ø CORTICAL	L (mm)	H (mm)
●	Ø2.90 mm	Ø3.00 mm	From 12 to 16*	2.00 / 4.00

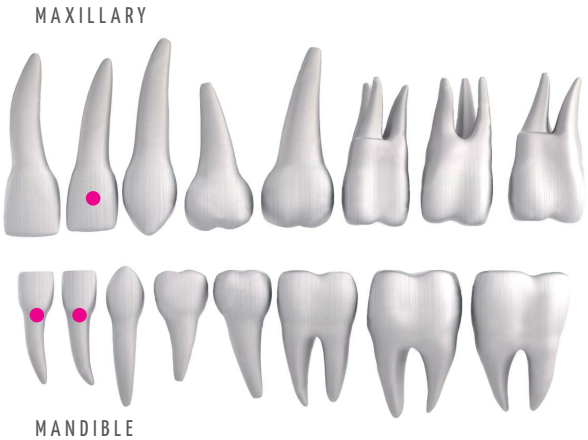
* The real length of the implant is 2 mm smaller than its description.

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.
- Gingival collar height (2 or 4 mm) should be chosen so the treated part (ADS) of the implant is totally placed in bone.
- Clean and properly sterilize surgical kit following the instructions.

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



● Ø3.00 mm

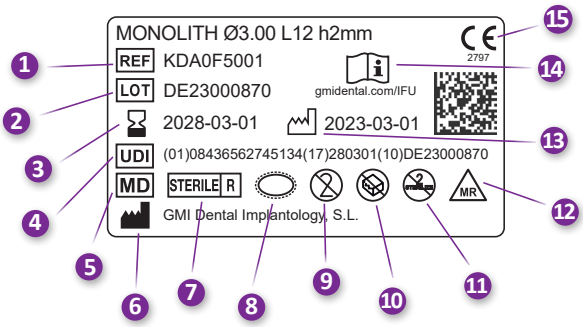
- Incisors
  (Except central maxillary incisors)

IMPLANT SYSTEM LABELLING DESCRIPTION

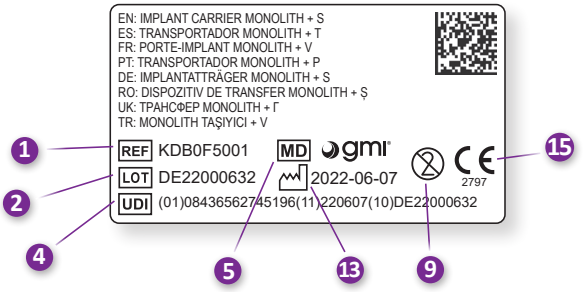
In the chart are detailed all the symbols that appear on the implant system labelling and packaging and their corresponding description:

1	REF	Reference
2	LOT	Batch code
3		Used-by-date
4	UDI	Unique device identifier
5	MD	Medical device
6		Manufacturer
7	STERILE R	Sterilized using gamma radiation
8		Single sterile barrier system with protective packaging outside
9		Single use only
10		Do not use if packaging is damaged or opened
11		Do not resterilize
12	MR	MR Conditional: Items do not pose any known hazards in a specific MR environment with specific conditions of use
13		Manufacturing date
14	gmidental.com/IFU	Electronic instructions for use
15	CE 2797	European conformity mark with a Notified Body intervention
16	CE	European conformity mark. Self-certifying
17	NON STERILE	Non-sterile
18	Rx Only	Sale by or on the order of a licensed dentist

Implant label



Attachments label



Connection and platform

Packaging

Attachments packaging

GMI® MONOLITH SURGICAL KIT

The **GMI® monolith 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. It has a incorporated stop at 5 mm depth.

• **Stepped drills:** They enable milling the bone gradually minimizing the increase in temperature. Moreover they facilitate the centering of the milling procedure. They have a incorporated stop adjusted to the length of the implant.

ABUTMENTS EXTRACTOR

Once the screw is removed, it enables unlocking the abutment of the implant easily. As an additional advantage it allows the abutment to be safely removed from patient's mouth.

CARRIER WRENCH

Once inserted correctly in the carrier connection 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. It is also available in HP connection.

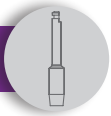
HEX-1,20 HEXAGONAL WRENCH

Once introduced in the hexagon socket part, it enables screwing and loosening the healing abutments, clinical screws and the ball abutments. It is designed both for manual use as well as coupled to the TI ratchet wrench.

GINGIVAL HEIGHT GAUGE / PARALLELIZER

Once inserted into the bone bed, after using the lanced drill, they allow to check the parallelism between the preparation and the rest of the structures or adjacent implants, as well as to check the height of the gingival tissue. The marks are 2 mm separated.

GINGIVAL PUNCH



Enables making Ø3.50 mm circular incisions directly into the soft tissue, avoiding having to do the flap technique to discover the implant bone bed.

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 of the prosthetic phase. See instructions for reference.

OPTIONAL SURGICAL INSTRUMENTS

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

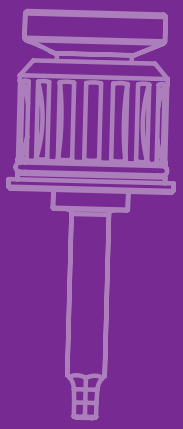
HP ADAPTOR WRENCH

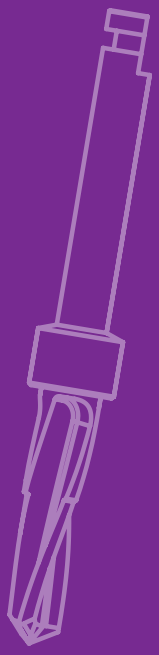
Adapter that allows using all the wrenches with a HP connection (hand-piece) manually or coupled to the TI ratchet wrench.

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





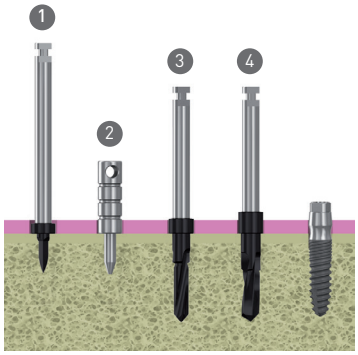
DRILLING SEQUENCES

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

- **Lanced drill**: 1,200-1,500 rpm.
- **Stepped drills**:
  - Ø2.00 / Ø2.50 mm ----------→ 900-1,200 rpm.
  - Ø2.50 / Ø2.80 mm ----------→ 500-700 rpm.

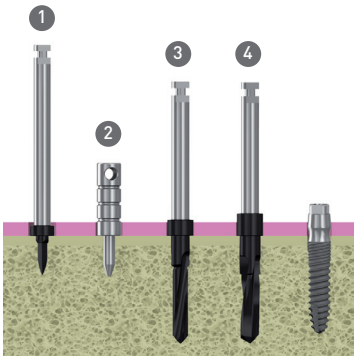
MONOLITH IMPLANT SEQUENCE Ø3.00 - L12 mm

1- Lanced drill (KYF0C1301)
2- Gingival height gauge (KYF0C0141)
3- Stepped drill Ø2.00-2.50 (KYF0C5251)
⚠ **4- Stepped drill Ø2.50-Ø2.80** (KYF0C5281)



MONOLITH IMPLANT SEQUENCE Ø3.00 - L14 mm

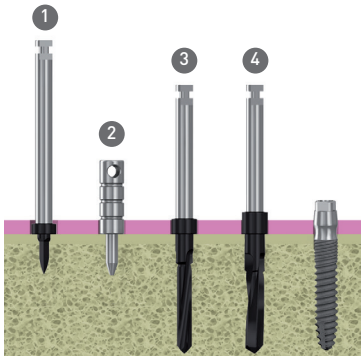
1- Lanced drill (KYF0C1301)
2- Gingival height gauge (KYF0C0141)
3- Stepped drill Ø2.00-2.50 (KYF0C5252)
⚠ **4- Stepped drill Ø2.50-Ø2.80** (KYF0C5282)



⚠ Optional for bone type III and type IV.

MONOLITH IMPLANT SEQUENCE Ø3.00 - L16 mm

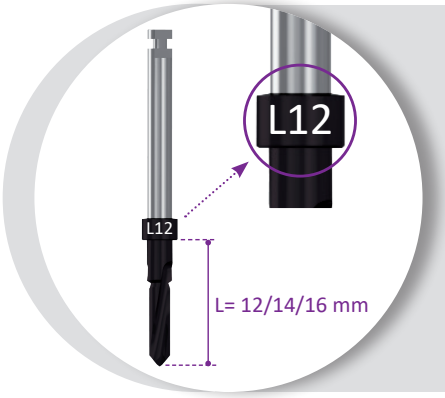
1- **Lanced drill** (KYF0C1301)
2- **Gingival height gauge** (KYF0C0141)
3- **Stepped drill Ø2.00-2.50** (KYF0C5253)
⚠ 4- **Stepped drill Ø2.50-Ø2.80** (KYF0C5283)



⚠ Optional for bone type III and type IV.

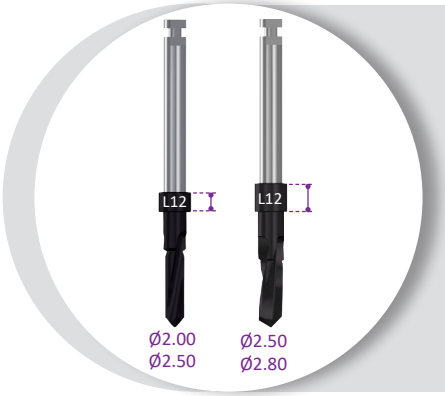
NOTE: Procedure recommended by **GMI**® cannot replace the judgement and the experience of the surgeon.

DIMENSIONS AND SELECTION OF DRILLS



Select the suitable drill

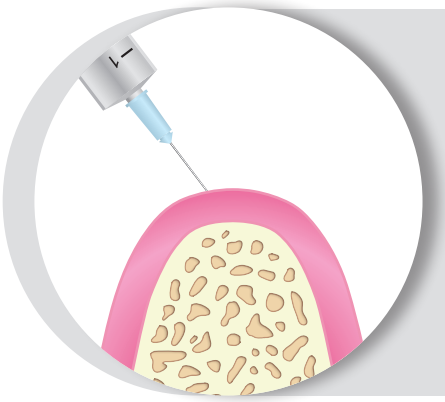
Select the drill depending on the length of the implant.
The length of the implant must match the marking that appears on the drill stop.



Differentiation of drills

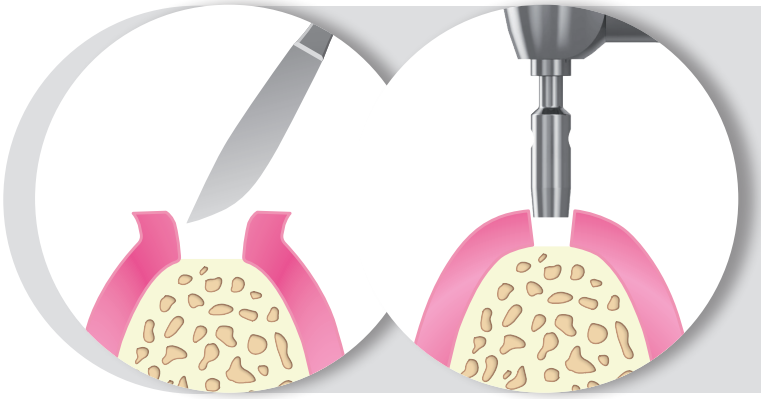
The length of the stop is different to be able to differentiate easily the Ø2.00 / Ø2.50 mm step drill from the Ø2.50 / Ø2.80 mm step drill.

BONE BED DRILLING



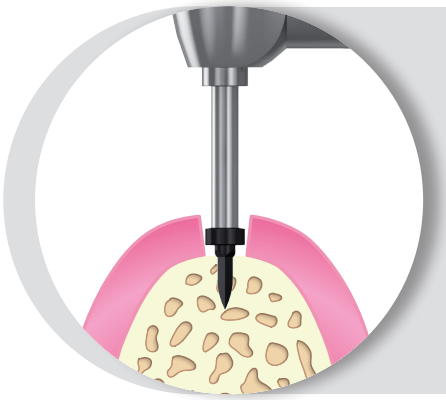
1. Anaesthetize

Apply infiltrative anaesthesia in soft tissues following standard clinical procedures.



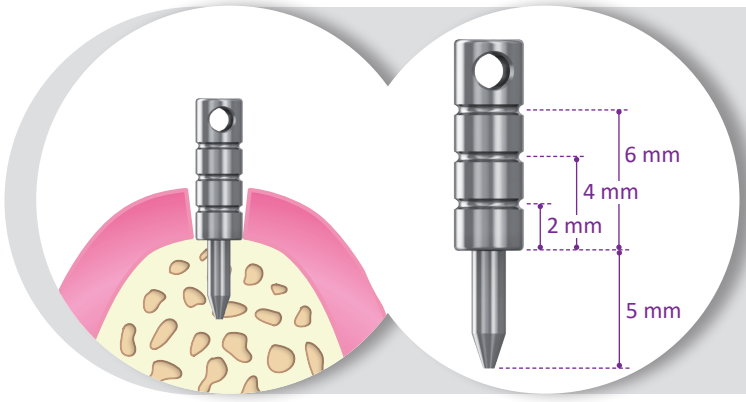
2. Perform soft tissue incision

Identify the anatomical area to respect and uncover the bone in the implant placement by making a crestal incision using a manual gingival punch with HP connection (Ref. KYL0C0142) for flapless technique or with a scalpel if use the flap technique.



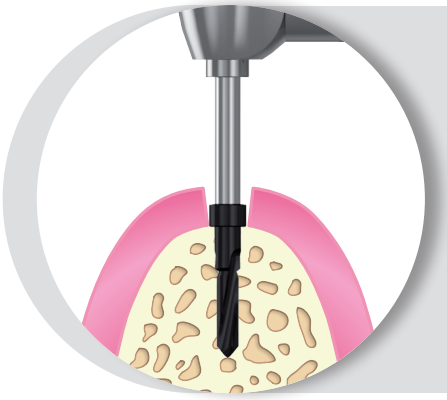
3. Mark osteotomy beginning

Set the engine speed between 1,200-1,500 rpm, depending on bone density, and use the lance-shaped drill with stop (Ref. KYF0C1301) to mark the bone and start the osteotomy. Use plenty of external cooling with saline solution at a low temperature.



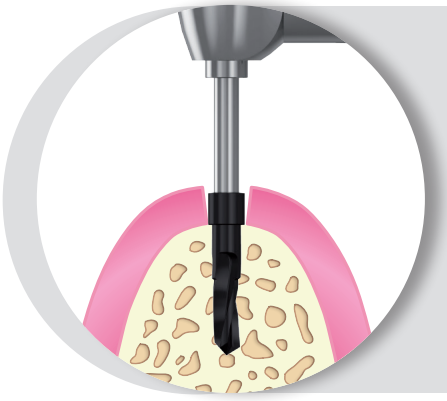
4. Check position and angulation

Introduce the gingival height gauge / parallelizer and check that the initial milling is in the correct position and angulation. Check the gingival tissue thickness with depth markings.



5. Perform initial drilling

Select the suitable drill to the length of the implant. Set the engine speed between 900 and 1,200 rpm, depending on bone density, and use the Ø2.00 / Ø2.50 mm step drill with stop (Ref. KYF0C5251/52/53) to determine the inclination and depth of the osteotomy. Use plenty of external cooling with saline solution at a low temperature.



6. Carry out the widening of the osteotomy

Select the suitable drill to the length of the implant. Set the engine speed between 500 and 700 rpm, depending on bone density, and use the Ø2.50 / Ø2.80 mm step drill with stop (Ref. KYF0C5281/82/83) to progressively widen the osteotomy. Use plenty of external cooling with saline solution at a low temperature.
The final drill can not be necessary with soft bones type III / IV.

IMPLANT INSERTION

1. Selection of the implant and initial check

Select the implant depending on the restoration type and the thickness of the soft tissue. The h=4 mm implants ara only indicated to perform over-denture restorations.

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

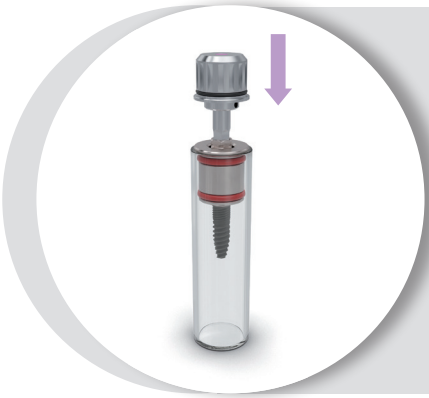
Open the tab on the box and remove the secondary packaging and adhesive labels identifying the product. Check the integrity of the secondary packaging. If some type of product manipulation is noticed please discard it.

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

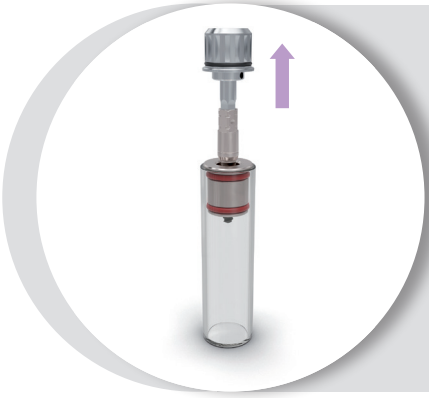
Hold the primary container vertically with the cap upwards and open the cap with a lateral movement.



5. Insert the carrier wrench into the implant

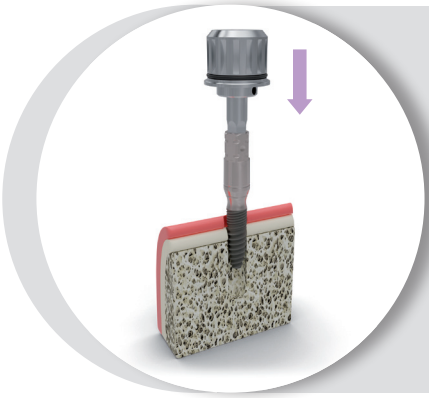
Keeping the container upright, insert the **monolith** carrier wrench for short wrench (Ref. KYLOF0139) inside the implant, taking into account correctly orienting the hex wrench and carrier until it stops.

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



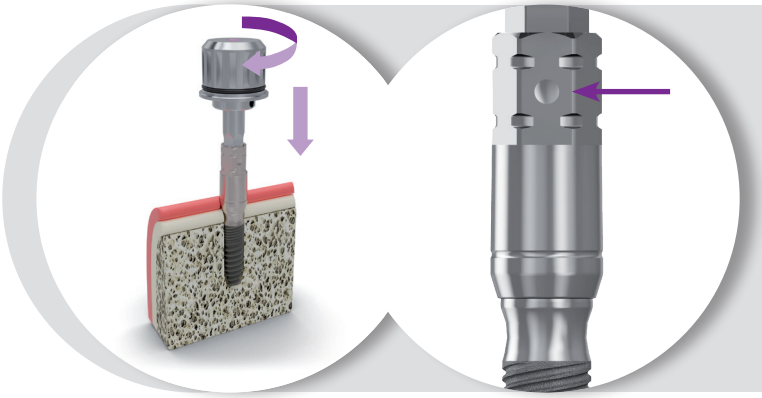
6. Extract the set from the primary container

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

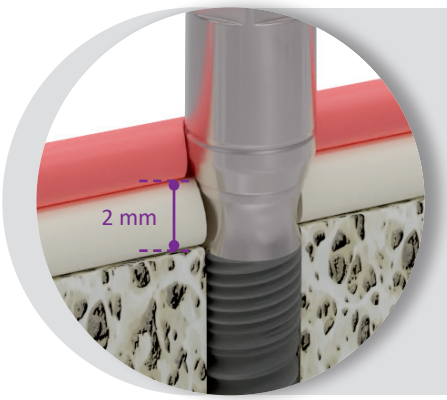
Perform the initial implant insertion manually in the bone bed prepared in the previous step.



8. Finish inserting the implant

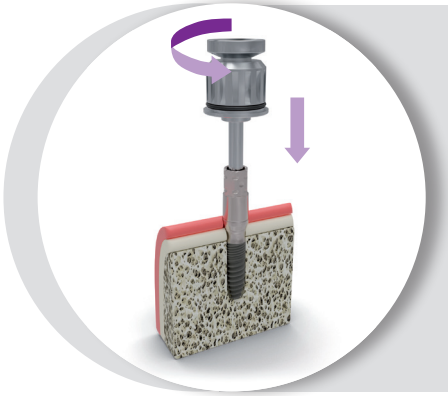
Finish inserting the implant with the TI torque ratchet wrench applying a torque of **35 N•cm**, make sure the treated part (ADS) of the implant is totally placed in bone. With the help of the reference marks on the carrier, orientate one of the faces of the square of the implant toward vestibular.

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



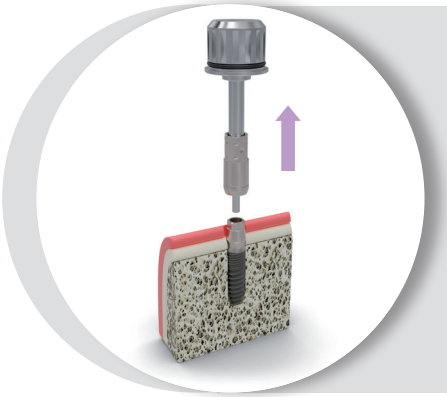
9. Position of the implant

The implants are placed with the level of the crestal bone between the treated area with ADS and the upper part of the polished collar.



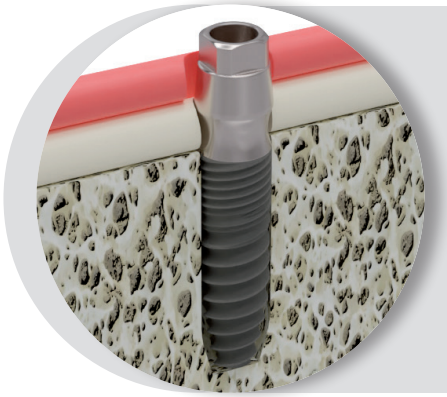
10. Loosen the screw

Insert the HEX-1.20 mm wrench (Ref. KYL0F0128), loosen and remove the screw from the abutment.



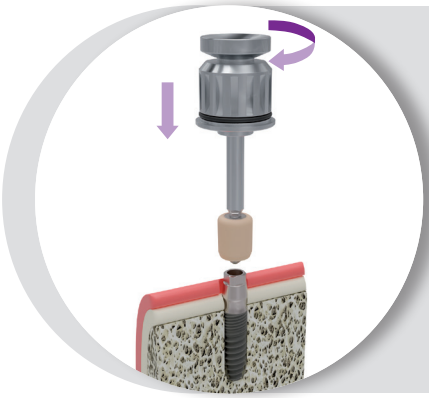
11. Disassemble carrier abutment

Insert the extractor wrench turning clockwise until implant carrier is disassembled from implant.
Remove implant carrier.



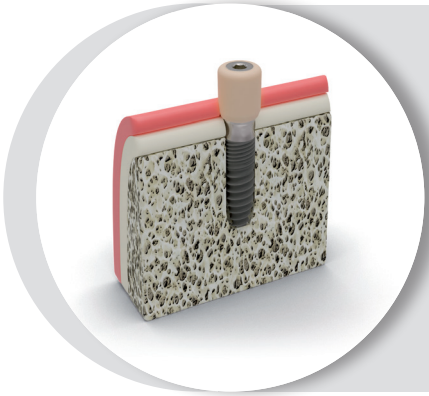
12. Check implant position

Check the implant is in the correct position.
Take a radiograph to verify the proper placement of the implant and attach it to the files.



13. Select and thread the healing abutment

Select the diameter of the healing abutment depending on the desired emergency profile.
Screw the selected abutment to the implant manually with the HEX-1.20 mm wrench (Ref. KYL0F0128) applying a torque of **15 N•cm**.



14. Check height and suture

Ensure the healing abutment is correctly seated in the implant.
Suture the soft tissues around the abutment and wait until the healing phase is over.

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06/2025