

THE FIRST HIGH BIOLOGICAL PERFORMANCE IMPLANT SYSTEM





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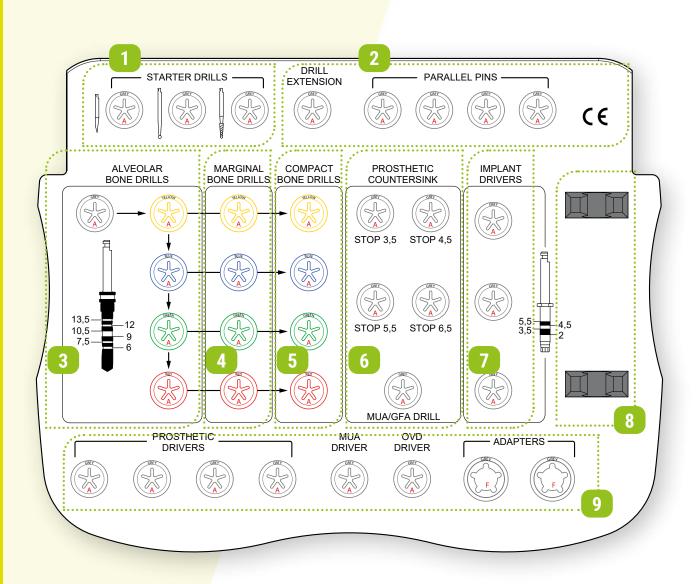
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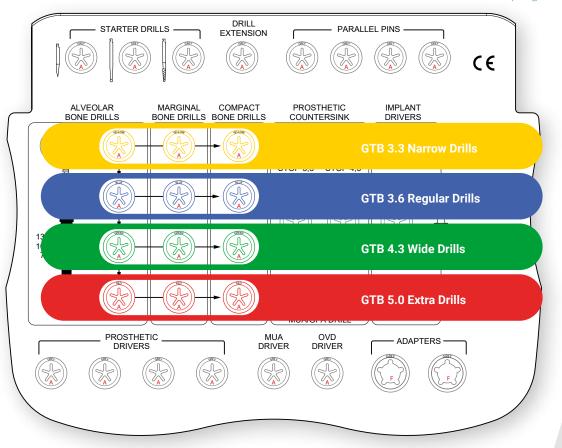
Description of the surgical kit

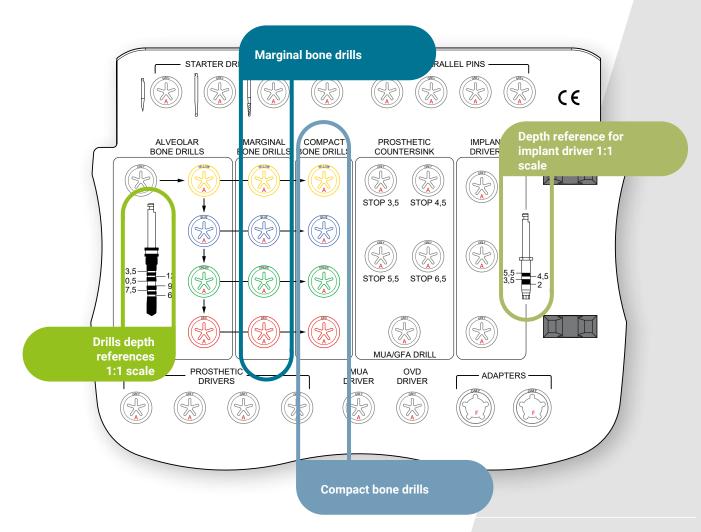


- 1 Starting drills
 2 Drill extension Parallel pins
 3 Alveolar bone drills

 4 Marginal bone drills
 5 Compact bone drills
 6 MUA/GFA countersink
 - 7 Implant driver 8 10-70 Ncm Torque ratchet 9 Prosthetic drivers







Milling tools description

The final drill diameter has to be selected based on the bone quality and, of course, based on the GTB implant diameter.

The working depth of the drill has to be selected based on the GTB implant length and in consideration of the juxta-crestal or 1.5 mm sub-crestal positioning.

Working speed: below 300 rpm (MAX. TORQUE 45 Ncm)

Indicative duration¹: 50 uses

¹ INDICATIVE DURATION OF CUTTING INSTRUMENTS:

The number of uses for each cutting instrument is only is indicative and refers to use in medium density bone. In case of drilling of thick and compact cortical bones, it is advisable not to exceed 10 working cycles with a single instrument since impaired cutting performance can lead to bone overheating.

This is particularly important for the first 3 drill diameters usually used and for the finishing instruments used in cortical bone, such as marginal bone drills.





The alveolar bone drill (\emptyset 2.5 - \emptyset 2.8 - \emptyset 3.6 - \emptyset 4.3) features a double-diameter design with a reduced apex (the first 3.0 mm of the tip) that allows for better implant grip with soft trabecular bone and makes it easier to centre larger drills. Single ring colour code.

COLOUR CODE YELLOW: NOMINAL Ø2.5 - APEX Ø2.2 COLOUR CODE BLUE: NOMINAL Ø2.8 - APEX Ø2.5 COLOUR CODE GREEN: NOMINAL Ø3.6 - APEX Ø3.3 COLOUR CODE RED: NOMINAL Ø4.3 - APEX Ø4.0

The compact bone drills ($\emptyset 3.0 - \emptyset 3.3 - \emptyset 4.0 - \emptyset 4.7$) feature a single-diameter design to allow positioning the implant at low torque and not to compress the blood clot during implant positioning. Double ring colour code.

COLOUR CODE YELLOW: NOMINAL ø3.0 COLOUR CODE BLUE: NOMINAL ø3.3 COLOUR CODE GREEN: NOMINAL ø4.0 COLOUR CODE RED: NOMINAL ø4.7



Milling tools description

The marginal bone drill has to be used when the bone is composed by thick and hard marginal bone.

In cases where the use of marginal bone drill is indicated, its diameter must correspond to the diameter of the GTB implant to be inserted (the marginal bone drill is slightly under dimensioned to prevent overpreparation).

The use of the marginal bone drill is very important when the treatment plan requires a 1.5 mm or more sub-crestal positioning, since the implant neck must be able to go under the marginal bone level without applying tension to the cortical bone.

COLOUR CODE YELLOW: NOMINAL ø3.2 COLOUR CODE BLUE: NOMINAL ø3.5 COLOUR CODE GREEN: NOMINAL ø4.2

COLOUR CODE RED: NOMINAL ø4.9

Working speed: below 50 rpm (MAX. TORQUE 45 Ncm)

Indicative duration¹: 50 uses

¹ INDICATIVE DURATION OF CUTTING INSTRUMENTS:

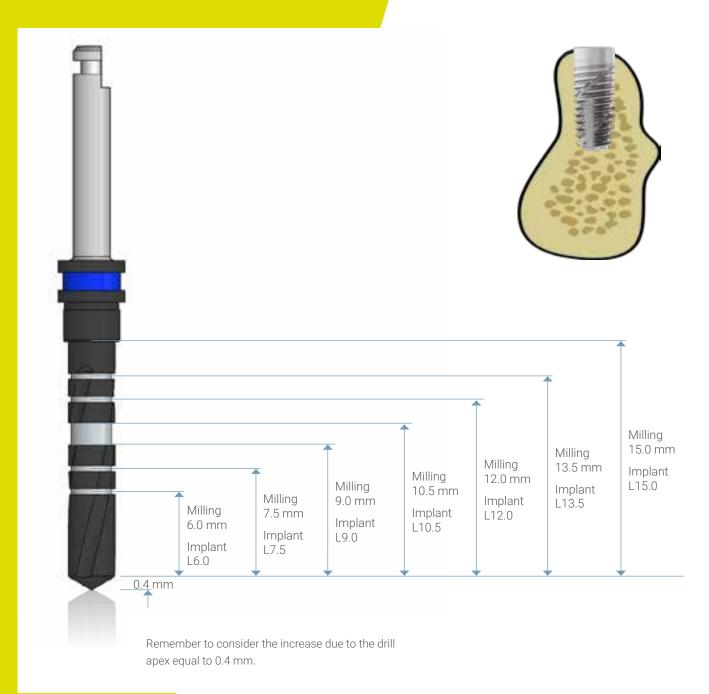
The number of uses for each cutting instrument is only is indicative and refers to use in medium density bone. In case of drilling of thick and compact cortical bones, it is advisable not to exceed 10 working cycles with a single instrument since impaired cutting performance can lead to bone overheating.

This is particularly important for the first 3 drill diameters usually used and for the finishing instruments used in cortical bone, such as marginal bone drills.



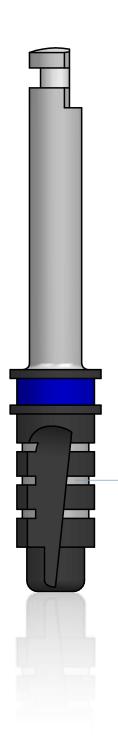


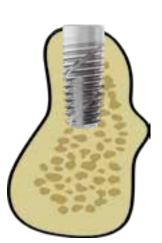
Depth references for juxta-crest positioning*



^{*} read the following surgical guidelines for the correct drill deepening in soft or medium density bone conditions



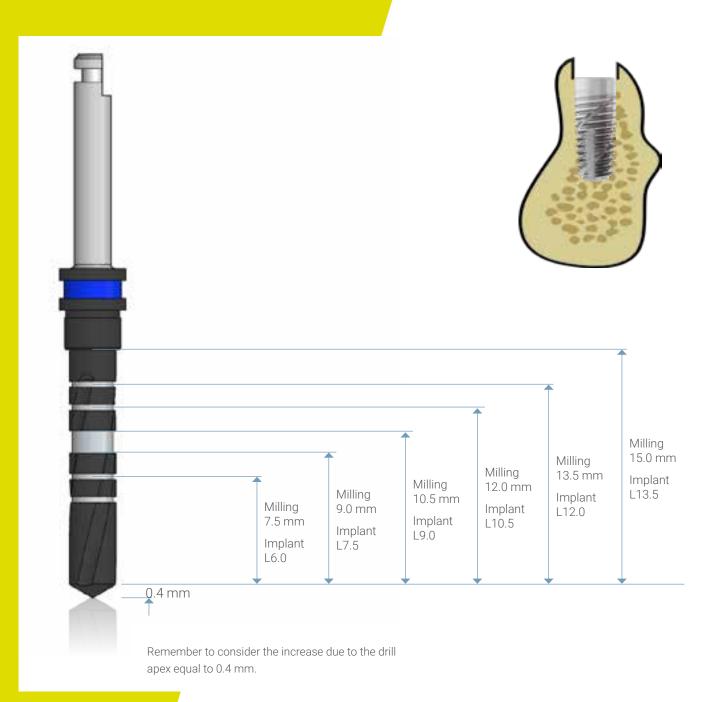




Bone crest level

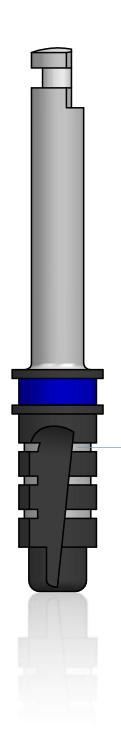
* With very compact bone quality or for a low torque implant positioning it's possible to sink the marginal bone drill until the next depth reference mark

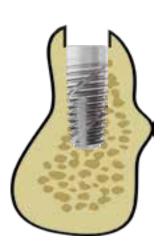
Depth references for 1.5 mm sub-crestal positioning*



^{*} read the following surgical guidelines for the correct drill deepening in soft or medium density bone conditions







Bone crest level

* With very compact bone quality or for a low torque implant positioning it's possible to sink the marginal bone drill until the next depth reference mark

Drill stops description

The alveolar bone drill stop provides precise control of the drilling depth during preparation of the implant bed for the insertion of **GTB dental implants**. The drilling depth indicated on the stop does not include the 0.4 mm increase, due to the apex of the drills. Always take this into account when planning the operation. The stops are available in 2 series: one for drills with diameters suitable for **GTB NARROW** and **GTB REGULAR** implants and the second for drills suitable for **GTB WIDE** implants. In this way, the mesio-distal overall measure of the

smallest diameter drills is not increased excessively, allowing for an easy preparation of the implant site with stop even when small implants are being positioned or when the gap is not wider than 4.5 mm. The stops are mounted on the drill with the help of mounting collars. Check the stop tightness regularly and replace the worn out stops.

DRILL STOP 36STP series

Made of surgical grade steel, they allow the perforation of the alveolar bone drill to be stopped at the preset length.

Available for the following work depth:

6.0 - 7.5 - 9.0 - 10.5 mm.

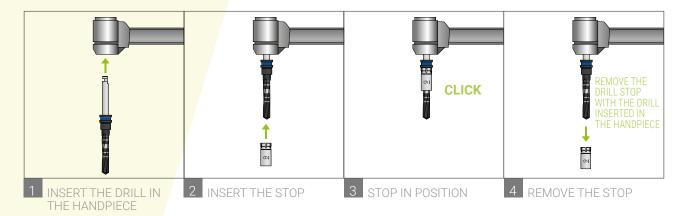
Adaptable to alveolar bone drill of following diameters: 2.0 - 2.5 - 2.8 - 3.0 - 3.3 mm.



Warning

Position and remove the stop with the drill correctly inserted in the contra-angle handpiece.

Length indication on the stop refers to the marking depth at which the drill will be stopped. The working depth must always be increased by 0.4 mm corresponding to the drill's apex.



Note: both series are supplied in an autoclavable box.



DRILL STOP 48STP series

Made of surgical grade steel, they allow the perforation of the alveolar bone drill to be stopped at the preset length.

Available for the following work depth: 6.0 - 7.5 - 9.0 - 10.5 mm.

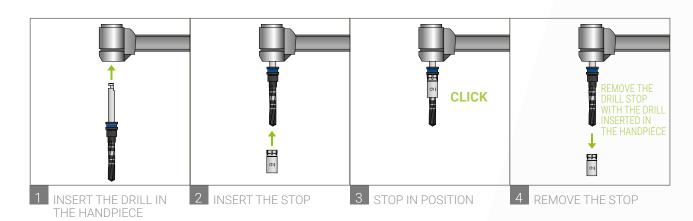
Adaptable to alveolar bone drill of following diameters: 3.6 - 4.0 mm.



Warning

Position and remove the stop with the drill correctly inserted in the contra-angle handpiece.

Length indication on the stop refers to the marking depth at which the drill will be stopped. The working depth must always be increased by 0.4 mm corresponding to the drill's apex.



Driver description

The **Direct Drivers** engage the implant directly and allow for picking, carrying and positioning the **GTB implant**. This allows to insert the implant with a greater torque in comparison to what is achievable with a mounting device, and it also simplifies the surgical phase since there is no mounting device to be removed once the positioning is complete. **Direct Drivers** are available in manual version and mechanical version and are suitable for both long and short contra-angle. All prosthetic components are screwed onto the implant by means of **Prosthetic Drivers** which are available for the manual version in three different heights and also in a mechanical version for contra-angles.

For further details, please refer to the implant instructions for use contained in the package.

All the manual instruments feature a bushing with a hole for the safety thread.



Implant drivers description

It allows for the picking, transport and positioning of the implant. Thanks to the reference mark on the driver, it is possible to phase the octagonal index of the implant in a desired and appropriate way. The phasing reference mark is always at a vertex of the implant's octagonal index. In addition, the driver has markings at 2.0 - 3.5 - 4.5 - 5.5 mm that allow to rapidly evaluate the soft tissue thickness and the adequate prosthetic components.

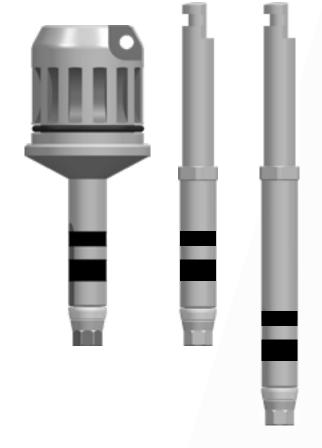
Available in manual version and in SHORT and LONG contra-angle suitable versions, compatible with the W&H Hexagon system. The maximum recommended positioning torque is 50 Ncm.



When cleaning the instruments do not use the brush on the Implant Driver retention system.

Maximum number of uses

50 uses.



Prosthetic drivers description

It allows to engage and screw all of the prosthetic components of the GTB implant system, including the surgical cover screw placed inside the cap of the sterile vial.

Available in SHORT and MEDIUM manual versions and in SHORT, MEDIUM and LONG mechanical versions, compatible with the W&H Hexagon system.

The tightening torque for surgical cover screws and healing abutments must not exceed 7 Ncm.

The tightening torque for temporary prosthetic components is 10-15 Ncm.

The tightening torque for final prosthetic components is 20-25 Ncm.











Maximum number of uses

50 uses.



Dynamic drivers description

The GTB system features a specific prosthetic driver for screwing angled respect to the implant axis. Useful solution for screwed prosthetic rehabilitations, this dynamic driver allows the driver to be angulated up to 29° respect to the implant axis.

PLEASE NOTE: the dynamic driver is not compatible with standard retaining screws and must only be used with the dynamic screws.

Available in SHORT and LONG versions.





50 uses.



Description of the torque ratchet

Torque ratchet with adjustable torque control

Check periodically the condition of the torque ratchet and verify the correct mobility of its moving parts.

All the components of the torque ratchet must be disassembled prior to cleaning and reassembled only before sterilization.

Please refer to the instructions for use and maintenance of the torque ratchet for the operations described above.

Adjustable torque from 10 Ncm to 70 Ncm.

Maximum number of uses

Maximum use: 5000 tightenings. We recommend servicing, to be performed exclusively by the manufacturer, once a year.





Treatment Plan

IMPLANT POSITION

The implant is the core of dental reconstruction. It is the foundation for planning the surgical procedure. Close communication between the patient, the dentist, the surgeon and the dental technician is essential to achieve the desired prosthetic result. In order to define the topographical situation, axial orientation and implant choice, it is advisable to perform the following steps:

- · Waxing/planning on the previously prepared study model.
- · Define the type of superstructure.

The waxing/planing can then be used as the basis for a customised x-ray or milling template and a temporary reconstruction.

Select the diameter, type, position and number of implants on a case-by-case basis, taking into account individual anatomical and spatial conditions (e.g. malpositioned or inclined teeth). The measurements given herein are to be understood as basic guidelines. Only if the minimum distances are observed is it possible to plan the restoration in such a way that the required oral hygiene measures can be implemented.

The final hard and soft tissue response is influenced by the position between the implant and the proposed reconstruction, which should therefore be based on the position of the implant-prosthetic connection.

The position of the implant can be regarded in three dimensions:

- · Mesio-distal
- · Vestibulo-palatal & Bucco-lingual
- · Corono-apical



Prosthetic components should always be axially loaded. Ideally, the longitudinal axis of the implant is aligned with the cusps of the opposite tooth. Extreme cusp formation should be avoided as this can result in non-physiological loads. Dental implants with vertical internal connections, such as the **GTB implant**, can guarantee significantly better biomechanical performance in comparison to horizontal connection im-

plants of flat-to-flat type only if the disparallelism between the implant axis and the prosthetic axis is equal or inferior to 15 degrees. The advantage of the **GTB dental implant** lies in the possibility of using shorter implants with reduced diameter in comparison to competitive implant systems, which in turn facilitates the correct positioning of the implant.



Mesio-distal implant position

The mesio-distal bone availability is an important factor for choosing the implant diameter as well as the inter-implant distances in the case of multiple implants.

Apply the following ground rules:

Rule 1

Distance to adjacent tooth at bone level: a minimal distance of 1.5 mm is required between the implant emergence and the adjacent tooth at bone crest level (mesial and distal) is required.

Rule 2

Distance to adjacent implants at bone level: a minimal distance of 2.0 mm between two adjacent implant emergences (mesio-distal) is required.







Vestibulo-palatal implant position

Palatal bone availability must be at least 1.0 mm thick in order to ensure stable conditions of hard and soft tissue. The minimal width of oro-facial crests is given in the **GTB implant** indication table. Choose the implant position and its oro-facial axis in such a way that the retaining screw channel of the prosthetic abutment is situated behind the incisal edge.

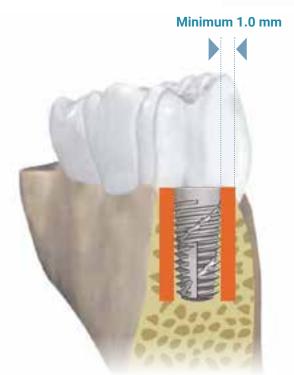
Thanks to the possibility of positioning the **GTB implants** at sub-crestal level, it is possible to sink the prosthetic platform until an adequate oro-facial dimension for placing the chosen implant is found. Once again, it is worth mentioning the biomechanical advantage of the **GTB implant** since it allows to

choose smaller diameter implants (to protect the palatal bone) of reduced lengths (allowing to position the prosthetic platform sub-crestally without having to perform particularly deep osteotomies).

Warning:

Bone augmentation procedure is indicated where the oro-facial bone wall is less than 1 mm thick or if there is no bone layer on one or more sides. Only dentists who have adequate experience in performing bone augmentation procedures should employ this technique.



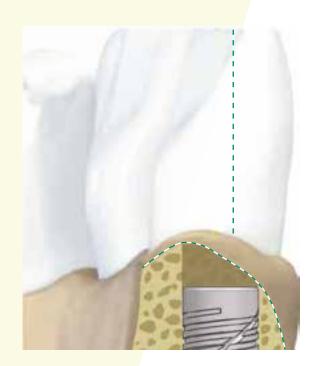


Corono-apical implant position

GTB dental implants allow for flexible corono-apical implant positioning, depending on the individual anatomy, implant site, the type of restoration planned and preferences. For aesthetic reasons, in the anterior area it is advisable to position the implant's prosthetic platform sub-crestally. In this case, the use of GTB NARROW Ø 3.3 mm or GTB REGULAR Ø 3.6 mm implants is recommended to maximize peri-implant bone volume. Ideally, the prosthetic coupling marginal point of the abutment should always be placed at least 2.0 mm from bone ridge to maintain the biologic width. In case of thin mucosal tissues, it is recommended to place the implant sub-crestally for at least 1.5 mm to allow, after post-insertion remodelling, bone regrowth above the GTB implant platform and subsequent increase of the biomechanical capacity of the bone-implant system while respecting the biologic width (in this case, the

prosthetic abutment's pathway is partly trans-osteal and partly trans-mucosal). If the bone crest is scalloped, position the implant with the prosthetic platform at the juxta-crestal level at the lowest point of the bone crest (anyway, it is possible to place the implant with prosthetic platform sub-crestally at any point, keeping in mind that the pre-finished prosthetic components have a trans-osteal/trans-mucosal pathway of 5.5 mm maximum).

The increase in depth of the osteotomy in relation to the length of the chosen **GTB implant** is 0.4 mm at most, allowing for maximum use of the available bone tissue also in corono-apical direction. The increase, albeit minimal, of the drills will always be present as the shape of the drill apex (conical) is different from that of the **GTB implant** apex (convex).





Corono-apical implant position

IMPLANT POSITIONING TABLE

Prosthetic platform positioning of GTB Implant	Minimum trans-mucosal height of the prosthetic component
JUXTA - CRESTAL	2.0 mm
SUB-CRESTAL 1.5 mm	3.5 mm
SUB-CRESTAL 2.5 mm	4.5 mm
SUB-CRESTAL 3.5 mm	5.5 mm

Reference table for respecting biological width. The table shows the minimum height related with implant platform positioning. The height can be greater but non smaller than the one specified.

If a shorter trans-mucosal height is required during prosthetic phase, it means that the coronal-apical position of the implant is incorrect or, in any case, it will not be possible to comply with the biological width.

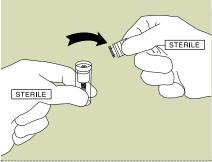
Implant packaging description

Choose the implant type, length and diameter and take the blister out of the NOT STERILE cardboard box. NOT STERILE The vial containing the implant is sterile and lodged in the blister. The NOT STERILE product description and the lot number are indicated on the label. Open the blister. NOT STERILE Take out the vial with the implant. 3 STERILE NOT STERILE Surgical cover screw is placed in the vial cap and sealed with a Tyvek film.

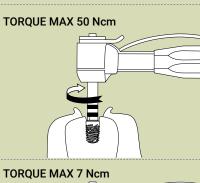


Implant packaging description

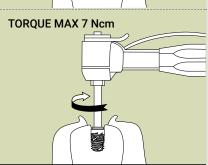
Gently open the vial cap (do not pull upwards).



6 Connect the Implant Driver (07GDD01; 07GDD02) and screw at low speed (10-15 rpm).



Pick the cover screw from the vial cap and screw it onto the implant with the Prosthetic Driver (07-EG05; 07-EG10; 07-EG20).



Bone quality classification

Classification of maxilla bone density (Lekholm&Zarb, 1985)









D1

Maxillary bone composed almost exclusively of dense cortical bone

D2

Thick and dense cortical bone surrounding the cancellous bone

D3

Thin layer of cortical bone surrounding cancellous bone with dense trabecular structure

D4

Very thin layer of cortical bone surrounding cancellous bone with trabecular structure

Typical anatomical distribution based on bone density (Misch&Judy, 1987; Misch, 1990)

BONE QUALITY	D1	D2	D3	D4
Anterior maxilla	0	25	65	10
Posterior maxilla	0	10	50	40
Anterior mandible	6	66	25	3
Posterior mandible	3	50	46	1

Compact bone	Medium bone	Soft bone
D1 and D2 verging to D1	D2 and D3	D4 and D3 verging to D4

31 BONE TYPE

HOMOGENEOUS COMPACT CORTICAL BONE

FRONT REGION OF AN ATROPHIC EDENTULOUS MANDIBLE

Advantages

- Good primary stability of the implant
- High bone-implant contact surface

Disadvantages

- Poor vascularisation
- Risk of overheating



Medium bone D2 and D3

THICK POROUS COMPACT CORTICAL BONE, HIGH-DENSITY CANCELLOUS BONE

FRONTAL AND LATERAL MANDIBULAR ARCH FRONTAL MAXILLARY ARCH (INCISAL AREA)



Advantages

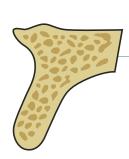
- Good primary stability of the implant
- Excellent vascularisation
- Easy implant site preparation

Disadvantages

None

THIN POROUS COMPACT CORTICAL BONE, LOW-DENSITY CANCELLOUS BONE

FRONTAL (LATERO-CANINE) AREA OF THE UPPER MAXILLARY ARCH, LATERAL AREA (MOLAR) OF THE MANDIBULAR ARCH



Advantages

Good vascularisation

Disadvantages

- Risk of over-preparation of the implant site
- Reduced bone-implant contact surface

D3 BONE TYPE



Soft bone D4 and D3 verging to D4

BONE TYPE

LOW-DENSITY CANCELLOUS BONE

MAXILLARY TUBER AREA



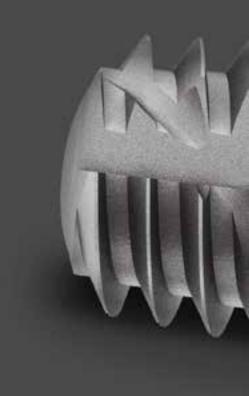
Advantages

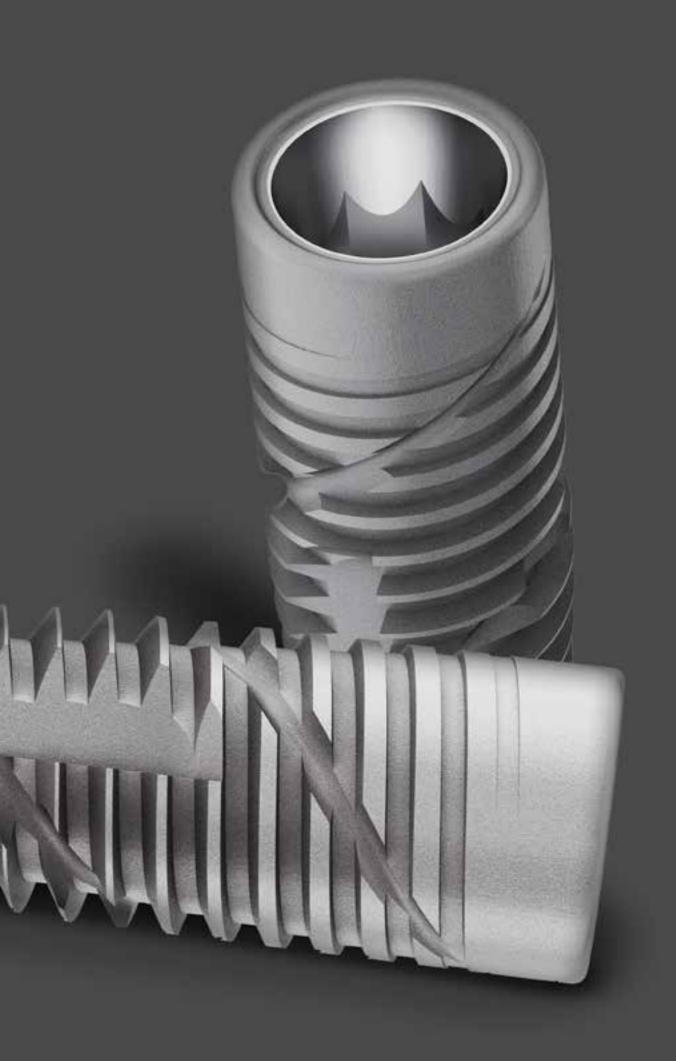
None

Disadvantages

- Risk of over-preparation of the implant site
- Reduced bone-implant contact surface
- Scarce primary stability of the implant

GB





GTB Implants

GTB NARROW IMPLANT SCREWS

Diameter 3.3 mm

Suitable for the anterior region or as a support implant in multiple rehabilitations, it is ideal for rehabilitating small-volume elements or in thin crest conditions.





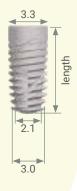




implant neck diameter

implant apical core diameter

> implant apical thread diameter



GTB NARROW Diameter 3.3 mm

Length 7.5 mm

code G3307



GTB NARROW

Diameter 3.3 mm

Length 9.0 mm code G3309



GTB NARROW

Diameter 3.3 mm Length 10.5 mm code G3310



GTB NARROW

Diameter 3.3 mm Length 12.0 mm code G3312



The surgical cover screw is included in the implant packaging



GTB REGULAR IMPLANT SCREWS

Diameter 3.6 mm

Standard diameter, ideal for single and multiple implant-prosthetic rehabilitations. This endosseous screw is suitable for post-extraction protocol and immediate loading. The option of a reduced length endosseous screw allows to always choose a prosthetically ideal position and axis and to deal with multiple rehabilitation protocols having angles that provide full mechanically and biologically safety.







V

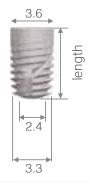


V









GTB REGULAR Diameter 3.6 mm Length 6.0 mm code G3606



GTB REGULAR Diameter 3.6 mm Length 7.5 mm code G3607



GTB REGULAR Diameter 3.6 mm Length 9.0 mm code G3609



GTB REGULAR Diameter 3.6 mm Length 10.5 mm code G3610



GTB REGULAR Diameter 3.6 mm Length 12.0 mm code G3612



The surgical cover screw is included in the implant packaging

GTB Implants

GTB WIDE IMPLANT SCREW

Diameter 4.3 mm

Large diameter implant, ideal for single and multiple implant-prosthetic rehabilitations involving low-quality bone and distal maxilla areas. The option of a reduced length endosseous screw allows to always choose a prosthetically ideal position and axis and to deal with multiple rehabilitation protocols having angles that provide full mechanically and biologically safety.





4.0

GTB WIDE

code G4306

Diameter 4.3 mm

Length 6.0 mm

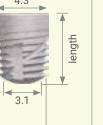




implant neck diameter

> implant apical core diameter

implant apical thread diameter



code G4307

GTB WIDE GTB WIDE Diameter 4.3 mm Diameter 4.3 mm Length 7.5 mm Length 9.0 mm



code G4309



GTB WIDE Diameter 4.3 mm Length 10.5 mm code G4310



GTB WIDE Diameter 4.3 mm Length 12.0 mm code G4312



The surgical cover screw is included in the implant packaging

Indications







GTB dental implants are indicated for oral endosseous placement in the maxilla and mandible and for functional and aesthetic rehabilitation of complete and partially edentulous patients (provided there are no particular contraindications or limitations, as shown below). GTB dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Within the scope of these indications,GTB implants are approved for immediate rehabilitation in cases of single tooth applications, complete or partial edentulous arch. Good primary stability and adequate occlusal loading are essential requirements.

In case of immediate rehabilitation, two or more adjacent implants should be prosthetically connected together. In case of immediate rehabilitation of completely edentulous patients, at least 4 implants must be connected together. Approximate duration of the healing phase for delayed rehabilitation is given below. The prosthetic rehabilitation used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (prosthetic components). In the following pages, detailed information is given about the indications, the required bone volume and the spacing between implants and adjacent teeth.

The innovative feature of **GTB implants** is that these endosseous screws have high biological performance and can therefore ensure adequate occlusal loading even when implants of reduced diameter and length are used or in any case not recommended com-

pared to a traditional implant system. This characteristic allows the surgical procedures to be carried out with a great deal of safety by being able to maintain much more margin from the anatomical limits and ensures that dental implants can be placed on bone tissues of greater volume (and greater vitality) in comparison to what is recommended when using traditional implant systems. For this reason, the objective to pursue when choosing the **GTB implant** diameter and length, is to keep most of the available bone tissue volume and perform the least invasive and simple surgical procedure possible.

The GTB REGULAR Ø 3.6 mm implant can easily be used in rehabilitations of single edentulia with a clinical crown of 10-12 mm, therefore in VI position in the maxilla, even when the available vertical bone requires the use of a **short GTB implant of 6.0mm** length. In addition, the concept of sub-crestal implant placement allows the diameter of the implant itself to be disconnected from the diameter of the prosthetic platform, thus permitting the clinic to choose the implant diameter that best suits the quality of the bone tissue: the GTB REGULAR Ø 3.6 mm implant is considered the implant of choice for the anterior section of the mandible, while the GTB WIDE Ø 4.3 mm implant becomes the implant of choice for the upper maxilla.

INDICATIONS FOR USE FOR GTB IMPLANTS

IMPLANT		INDICATION	MINIMAL VESTIBULAR- PALATAL SPACE	MINIMAL MESIO- DISTAL SPACE
GTB NARROW Ø 3.3 mm	Cursull Control	Narrow crests and interdental spaces. Recommended for the rehabilitation of lower incisors and lateral upper incisors	5.3 mm	6.3 mm
GTB REGULAR Ø 3.6 mm		Rehabilitation of single, partial or complete edentulias of all maxilla region. Recommended for compact bone	5.6 mm	6.6 mm
GTB WIDE Ø 4.3 mm		Rehabilitation of single, partial or complete edentulias of all maxilla region. Recommended for post-extractive alveoli and soft bone	6.3 mm	7.3 mm

Indications

Specific indications for small diameter implants GTB NARROW Ø 3.3 mm

The **GTB implant** does not follow the general rule of the competitive implant systems to use the largest possible implant diameter. With the **GTB implant system** it is possible to use **GTB REGULAR** Ø 3.6 mm diameter both in the incisal and the distal regions of the maxilla. However, to further facilitate the use of **GTB implant** it is possible to choose a reduced implant diameter - **GTB NARROW** Ø 3.3 mm - which allows for an easier placing of the implant in regions with scarce bone volumes, provided the loading conditions are adequate.

GTB NARROW Ø 3.3 mm implant is ideal for the rehabilitation of incisors in the mandible and lateral incisors in the maxilla. In case of application in regions with high occlusal loading, it is always better to choose the **GTB REGULAR** Ø 3.6 mm implant. If it is decided to use the **GTB NARROW** Ø 3.3 mm implant, this will have to be an auxiliary implant, used together with the **GTB REGULAR** Ø 3.6 mm implants or **GTB WIDE** Ø 4.3 mm implants to support prosthetic rehabilitations on multiple implants.

It is recommended to insert **GTB NARROW** Ø 3.3 mm implants in the molar regions of the maxilla.

Specific indications for short GTB implants of 6.0 mm

length

Thanks to their high biological performance, the **short GTB implants** of 6.0 mm length have no particular contraindications. They can also be used for rehabilitation also in case of a single edentulia. However, due to the limited available surface, great caution should be taken when those are used in post-extraction protocols with immediate or early loading demands, because the achieved mechanical primary stability is lower than in implants of greater length.

Contraindications

Serious internal medical problems, bone metabolism disturbances, uncontrolled bleeding disorders, inadequate wound healing capacity, poor oral hygiene, incomplete maxillary and mandibular growth, poor general health conditions, uncooperative, unmotivated patient, drug or alcohol abuse, psychoses, prolonged and therapy-resistant functional disorders, xerostomia, weakened immune system, illnesses requiring periodic use of steroids, titanium allergy, uncontrollable endocrine disorders.

Relative contraindications

Previously irradiated bone, diabetes mellitus, anticoagulation drugs/ haemorrhagic diathesis, bruxism, parafunctional habits, unfavourable anatomic bone conditions, tobacco abuse, uncontrolled periodontitis, temporomandibular joint disorders, treatable pathologic diseases of the mandible/maxilla and changes in the oral mucosa, pregnancy, inadequate oral hygiene.

Local contraindications

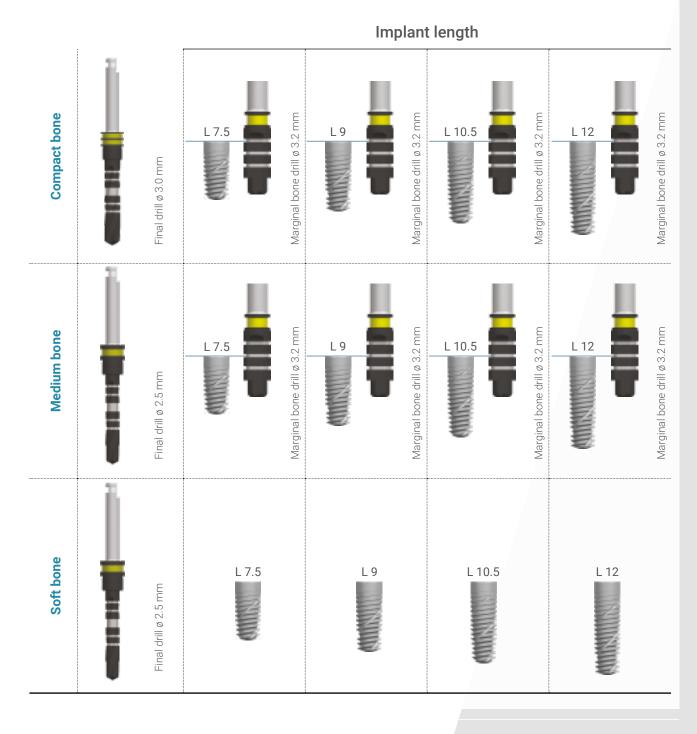
Inadequate bone volume and/or quality, apical root remnants.

General indications

1	Check that all necessary instruments are available and in perfect working condition. It is advisable to keep an adequate stock of implants and sterile spare instruments available.
2	Do not use cutting instruments more than 10 times on compact bones and more than 50 times on medium bones.
3	Ensure proper cooling of drills with pre-cooled (5°C/41°F) sterile saline solution (NaCl) or Ringer's solution.
4	Do not exceed the speed indications for drills 200-300 rpm.
5	Use drills in ascending order of their diameter and avoid considerable diameter changes when drilling compact bone (always use drills of intermediate diameter in compact bone).
6	Apply only light pressure and an intermittent milling technique (or 'to and fro' movement).

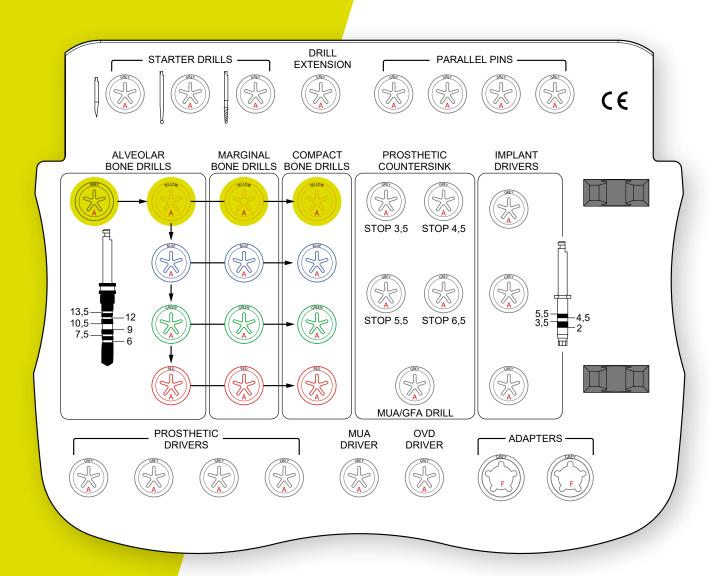


GTB Narrow Ø 3.3 mm Final drills sheet



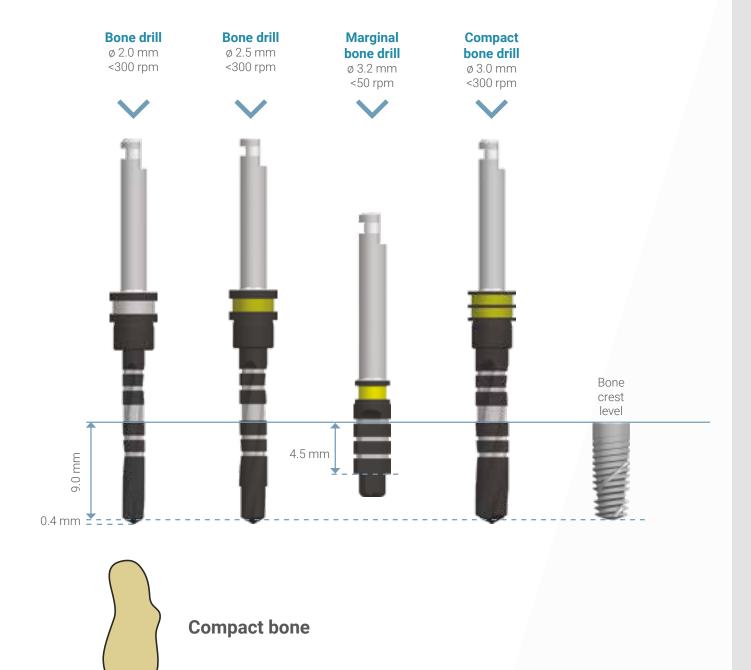


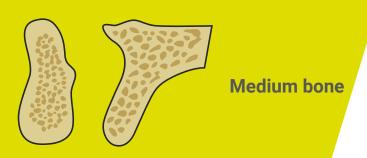
Compact bone

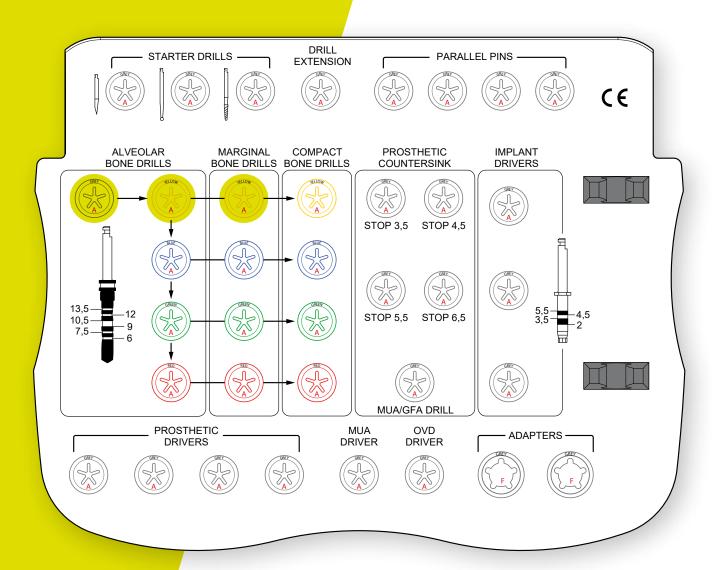




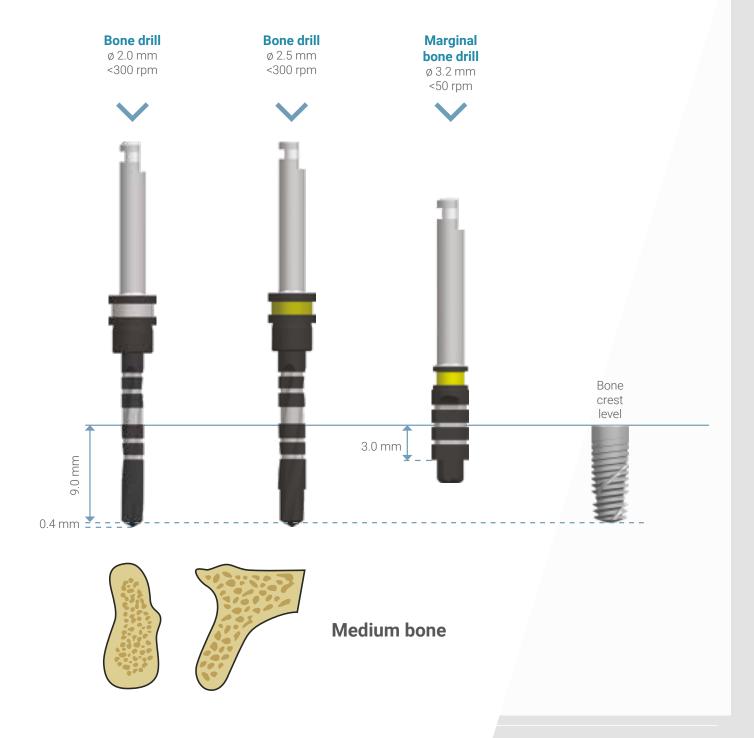
Example for L 9.0 mm implant length and juxta-crestal positioning

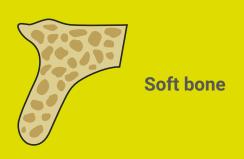


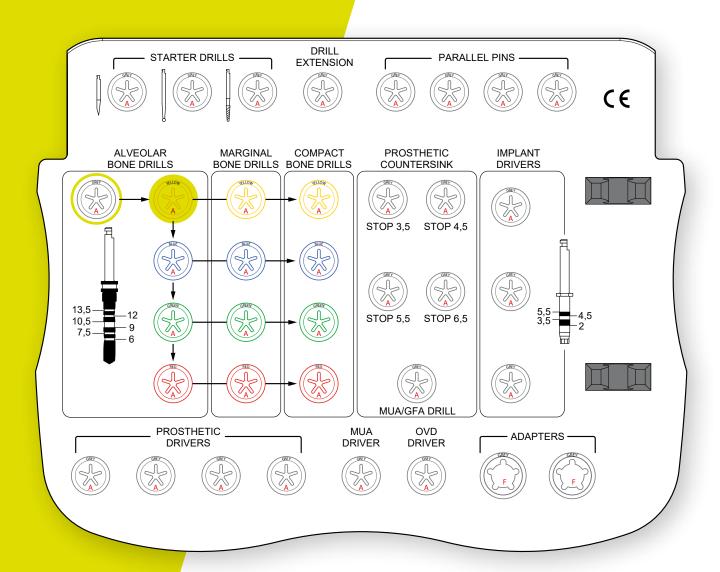




Example for L 9.0 mm implant length and juxta-crestal positioning

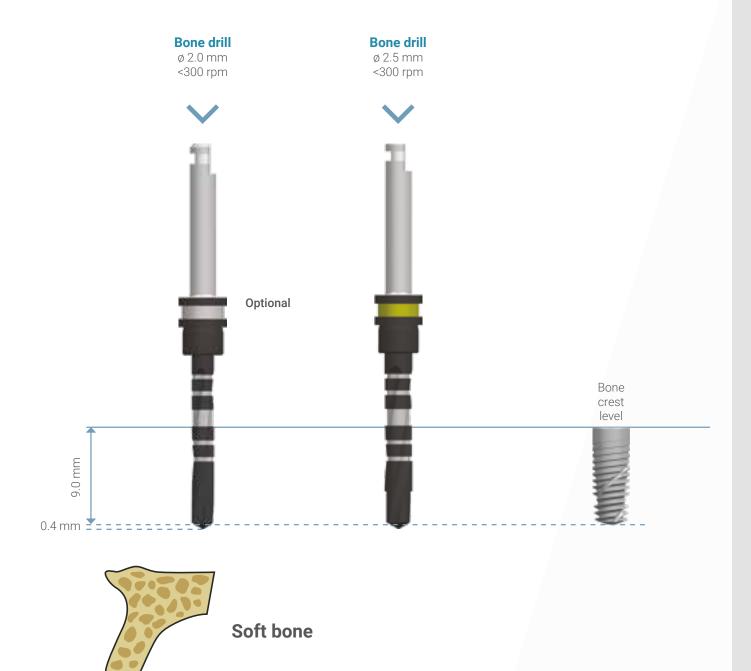






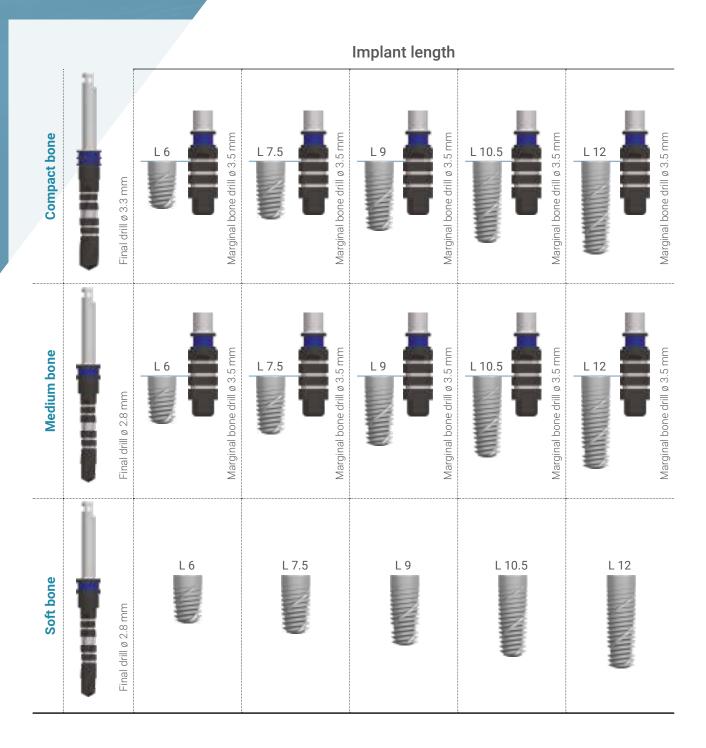


Example for L 9.0 mm implant length and juxta-crestal positioning



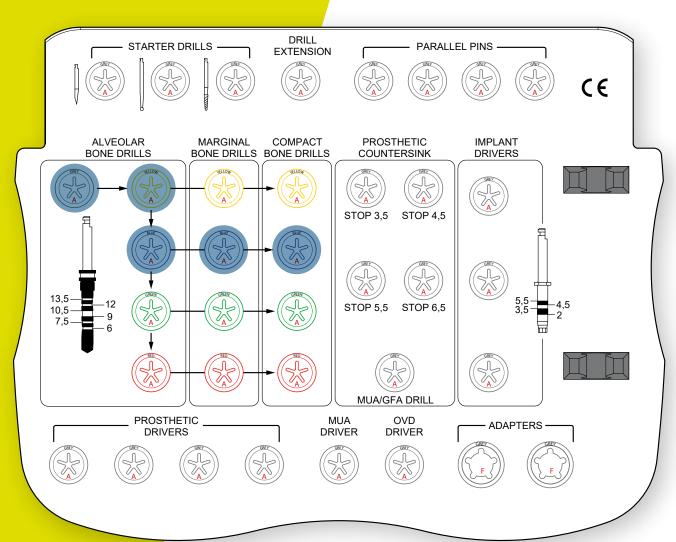
Final drills sheet GTB Regular Ø 3.6 mm



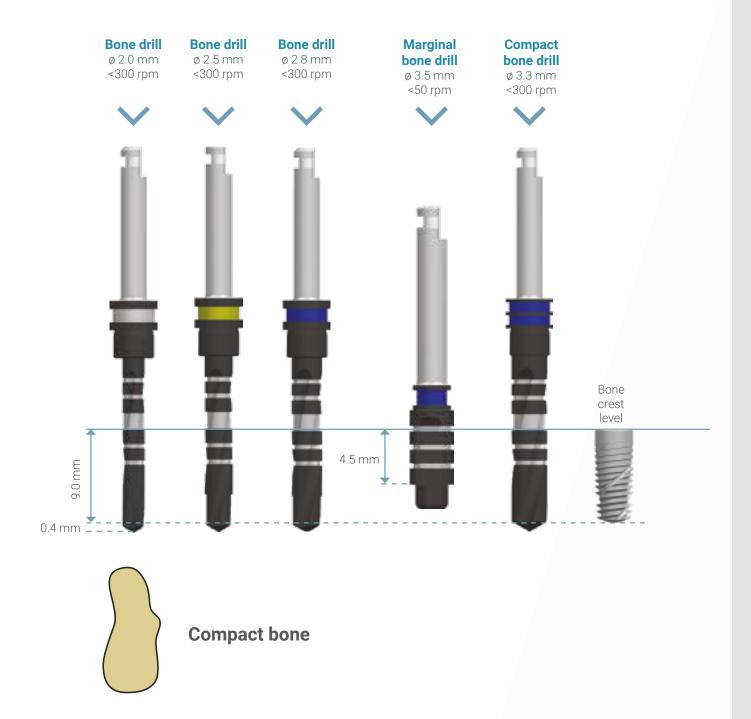


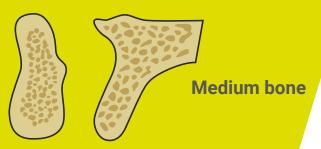


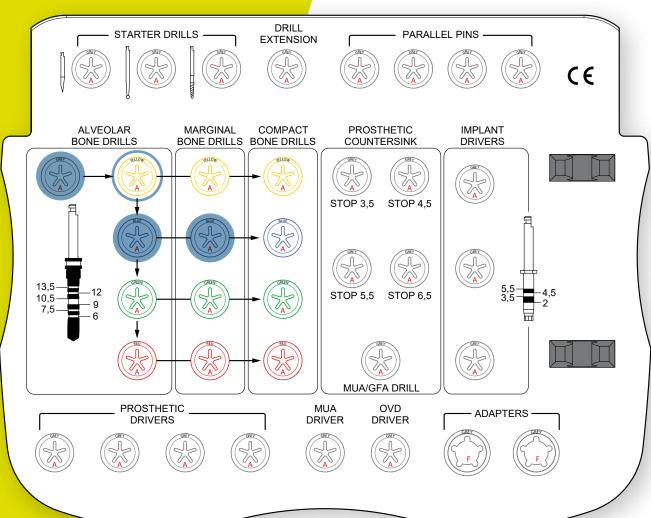
Compact bone









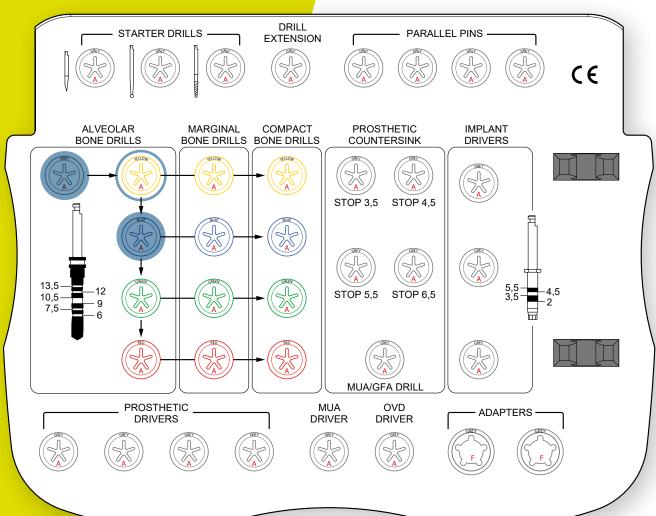








Soft bone

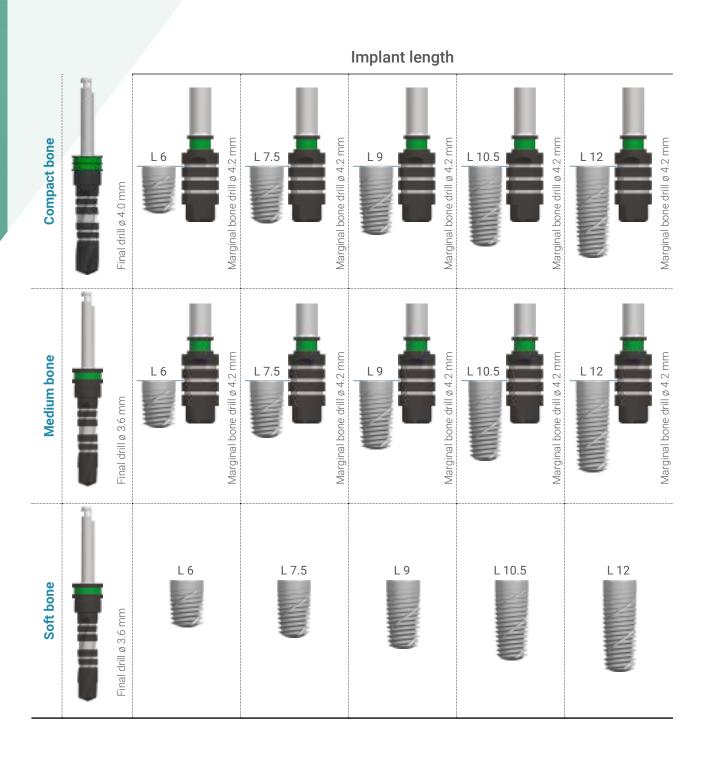






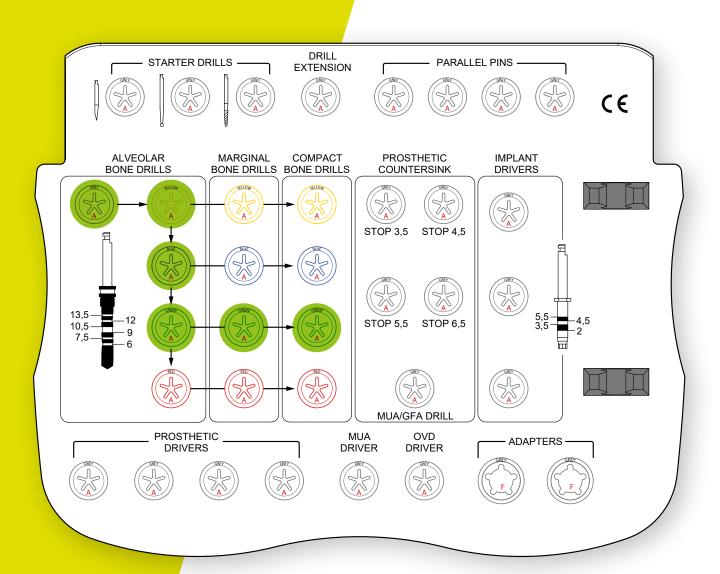
Final drills sheet GTB Wide Ø 4.3 mm



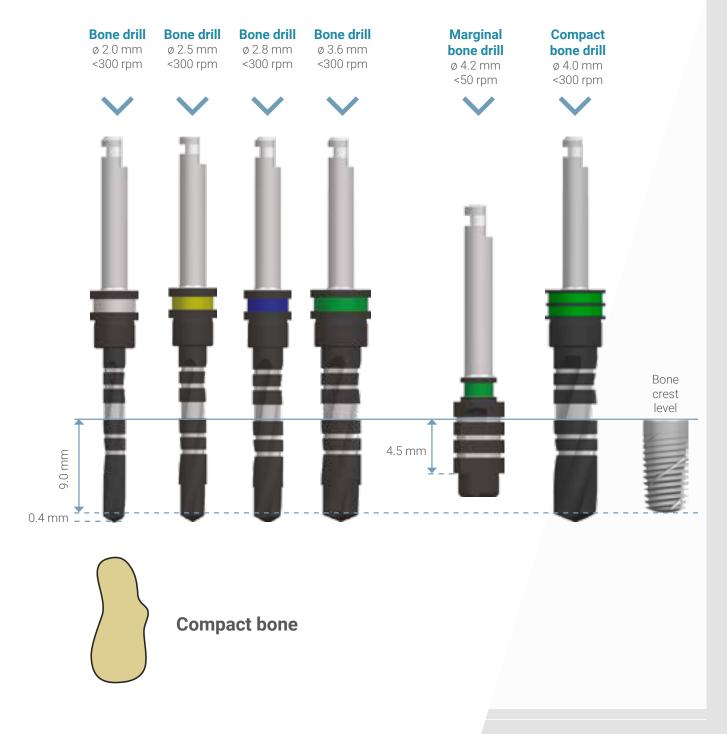


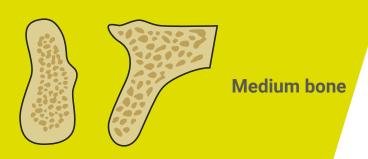


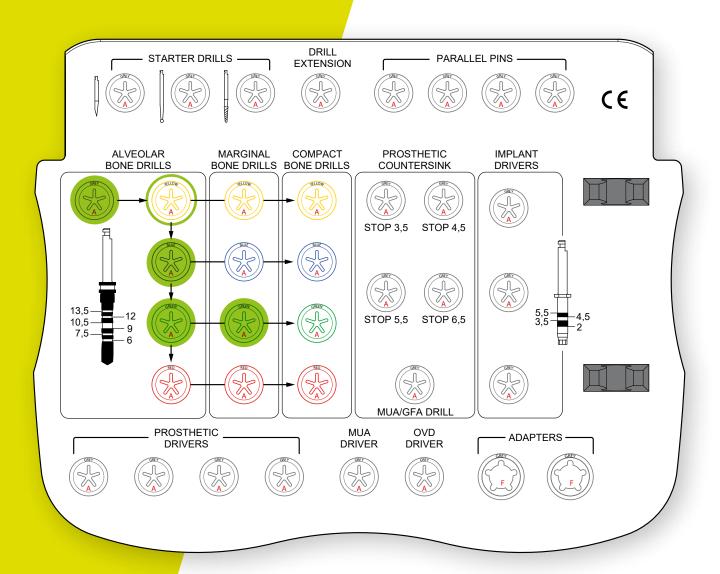
Compact bone



Example for L 9.0 mm implant length and juxta-crestal positioning





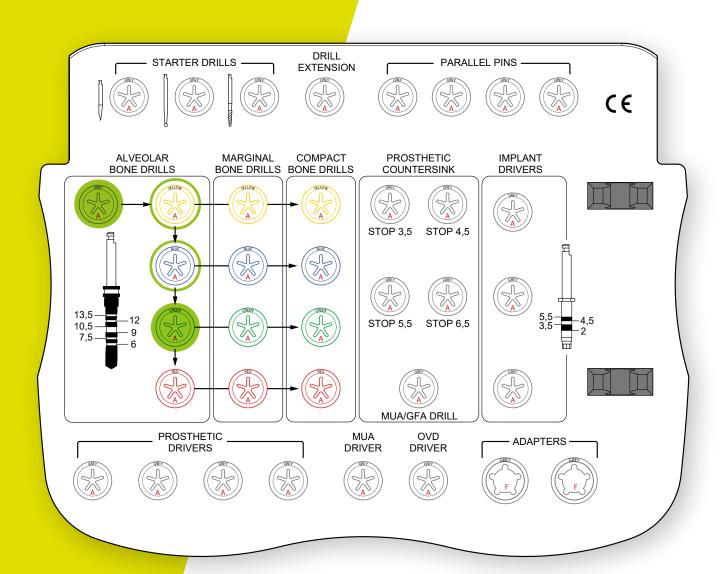


Example for L 9.0 mm implant length and juxta-crestal positioning





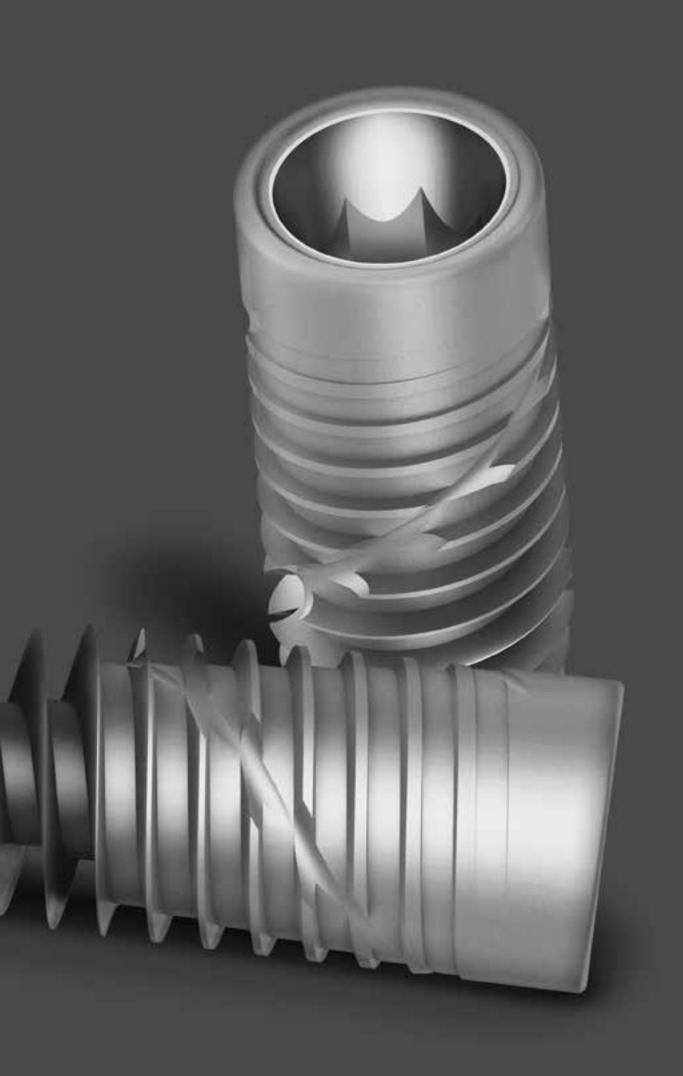
Soft bone



Example for L 9.0 mm implant length and juxta-crestal positioning





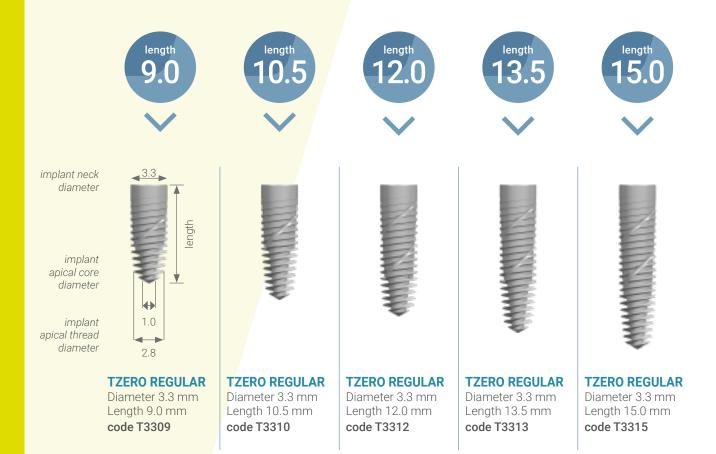


GTB-TZERO Implants

GTB-TZERO NARROW IMPLANT SCREWS

Diameter 3.3 mm

Suitable for the anterior region or as a support implant in multiple rehabilitations, it is ideal for rehabilitating small-volume elements or in thin crest conditions.

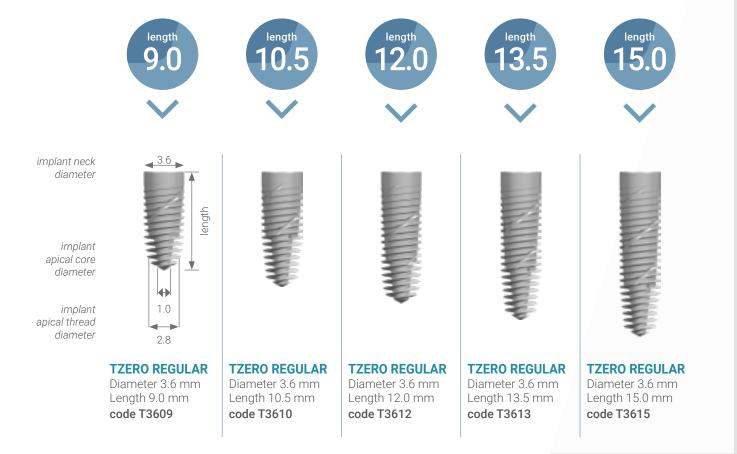




GTB-TZERO REGULAR IMPLANT SCREWS

Diameter 3.6 mm

Standard diameter, ideal for single and multiple implant-prosthetic rehabilitations. This endosseous screw is suitable for post-extraction protocol and immediate loading. The option of a reduced length endosseous screw allows to always choose a prosthetically ideal position and axis and to deal with multiple rehabilitation protocols having angles that provide full mechanically and biologically safety.



GTB-TZERO Implants

GTB-TZERO WIDE IMPLANT SCREWS

Diameter 4.3 mm

Large diameter implant, ideal for single and multiple implant-prosthetic rehabilitations involving low-quality bone and distal maxilla areas. This endosseous screw is suitable for post-extraction protocol and immediate loading. The option of a reduced length endosseous screw allows to always choose a prosthetically ideal position and axis and to deal with multiple rehabilitation protocols having angles that provide full mechanically and biologically safety.





GTB-TZERO EXTRA IMPLANT SCREWS

Diameter 5.0 mm

Large-diameter implant ideal for single and multiple implant-prosthetic rehabilitations with low-quality bone, distal maxillary areas and for post-extraction dental alveoli of significant volume. This endosseous screw is suitable for post-extraction protocol and immediate loading. The option of a reduced length endosseous screw allows to always choose a prosthetically ideal position and axis and to deal with multiple rehabilitation protocols having angles that provide full mechanically and biologically safety.



Indications

GTB TZERO dental implants are indicated for oral endosseous placement in the maxilla and mandible and for functional and aesthetic rehabilitation of complete and partially edentulous patients (provided there are no particular contraindications or limitations, as shown below). GTB TZERO dental implants are designed to be used for immediate or early insertion following extraction or loss of natural teeth. Within the scope of these indications, GTB implants are approved for immediate reconstruction in cases of single tooth applications, complete or partial edentulous arch. Good primary stability and adequate occlusal loading are essential requirements.

In case of immediate reconstruction, two or more adjacent implants should be prosthetically connected together. In case of immediate reconstruction of completely edentulous patients, at least 4 implants must be connected together. Approximate duration of the healing phase for delayed rehabilitation is given below. The prosthetic rehabilitation used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (prosthetic components). In the following pages, detailed information is given about the indications, the required bone volume and the spacing between implants and adjacent teeth.

The innovative feature of GTB TZERO implants is that these endosseous screws have high biological performance and can therefore ensure adequate occlusal loading even when implants of reduced diameter and length are used or in any case not recommended compared to a traditional implant system. This characteristic allows the surgical procedures to be carried out with a great deal of safety by being able to maintain much more margin from the anatomical limits and ensures that dental implants can be placed on bone tissues of greater volume (and greater vitality) in comparison to what is recommended when using traditional implant systems. For this reason, the objective to pursue when choosing the GTB TZERO implant diameter and length, is to keep most of the available bone tissue

volume and perform the least invasive and simple surgical procedure possible.

Since the GTB TZERO implant is designed for immediate loading, it is recommended to always use implants of the appropriate length to ensure proper primary stability at immediate loading, but at the same time to follow the guidelines according to the choice of implant diameter.

In fact, the concept of sub-crestal implant positioning allows the diameter of the implant itself to be disconnected from the diameter of the prosthetic platform, allowing the clinician to choose the implant diameter most suited to the quality of the bone tissue: the GTB TZERO REGULAR Ø 3.6 mm is considered the implant of choice for the anterior section of the mandible, while the GTB TZERO WIDE Ø 4.3 mm implant becomes the implant of choice for the upper maxilla. The GTB TZERO EXTRA Ø 5.0 mm remains the implant of choice for post-extraction in the posterior maxilla.







INDICATIONS OF USE FOR GTB-TZERO SYSTEMS

IMPLANT SCREW		INDICATIONS	MINIMAL VESTIBULAR- PALATAL SPACE	MINIMAL MESIO- DISTAL SPACE
GTB-TZERO NARROW Ø 3.3 mm		Narrow crests and interdental spaces. Recommended for the rehabilitation of lower incisors and lateral upper incisors	5.3 mm	6.3 mm
GTB-TZERO REGULAR Ø 3.6 mm		Rehabilitation of single, partial or complete edentulias of all maxilla region. Recommended for compact bone	5.6 mm	6.6 mm
GTB-TZERO WIDE Ø 4.3 mm		Rehabilitation of single, partial or complete edentulias of all maxilla region. Recommended for post-extractive alveoli and soft bone	6.3 mm	7.3 mm
GTB-TZERO EXTRA Ø 5.0 mm		Rehabilitation of single, partial or complete edentulias of all maxilla region. Recommended for post-extractive alveoli and soft bone in the molar region	7.0 mm	8.0 mm

Indications

Specific indications for small diameter implants GTB NARROW Ø 3.3 mm

The **GTB implant** does not follow the general rule of the competitive implant systems to use the largest possible implant diameter. With the **GTB implant system** it is possible to use **GTB REGULAR** Ø 3.6 mm diameter both in the incisal and the distal regions of the maxilla. However, to further facilitate the use of **GTB implant** it is possible to choose a reduced implant diameter - **GTB NARROW** Ø 3.3 mm - which allows for an easier placing of the implant in regions with scarce bone volumes, provided the loading conditions are adequate.

GTB NARROW Ø 3.3 mm implant is ideal for the rehabilitation of incisors in the mandible and lateral incisors in the maxilla. In case of application in regions with high occlusal loading, it is always better to choose the **GTB REGULAR** Ø 3.6 mm implant. If it is decided to use the **GTB NARROW** Ø 3.3 mm implant, this will have to be an auxiliary implant, used together with the **GTB REGULAR** Ø 3.6 mm implants or **GTB WIDE** Ø 4.3 mm implants to support prosthetic rehabilitations on multiple implants.

It is recommended to insert **GTB NARROW** Ø 3.3 mm implants in the molar regions of the maxilla.

Specific indications for short GTB implants of 6.0 mm

length

Thanks to their high biological performance, the **short GTB implants** of 6.0 mm length have no particular contraindications. They can also be used for rehabilitation also in case of a single edentulia. However, due to the limited available surface, great caution should be taken when those are used in post-extraction protocols with immediate or early loading demands, because the achieved mechanical primary stability is lower than in implants of greater length.

Contraindications

Serious internal medical problems, bone metabolism disturbances, uncontrolled bleeding disorders, inadequate wound healing capacity, poor oral hygiene, incomplete maxillary and mandibular growth, poor general health conditions, uncooperative, unmotivated patient, drug or alcohol abuse, psychoses, prolonged and therapy-resistant functional disorders, xerostomia, weakened immune system, illnesses requiring periodic use of steroids, titanium allergy, uncontrollable endocrine disorders.

Relative contraindications

Previously irradiated bone, diabetes mellitus, anticoagulation drugs/ haemorrhagic diathesis, bruxism, parafunctional habits, unfavourable anatomic bone conditions, tobacco abuse, uncontrolled periodontitis, temporomandibular joint disorders, treatable pathologic diseases of the mandible/maxilla and changes in the oral mucosa, pregnancy, inadequate oral hygiene.

Local contraindications

Inadequate bone volume and/or quality, apical root remnants.

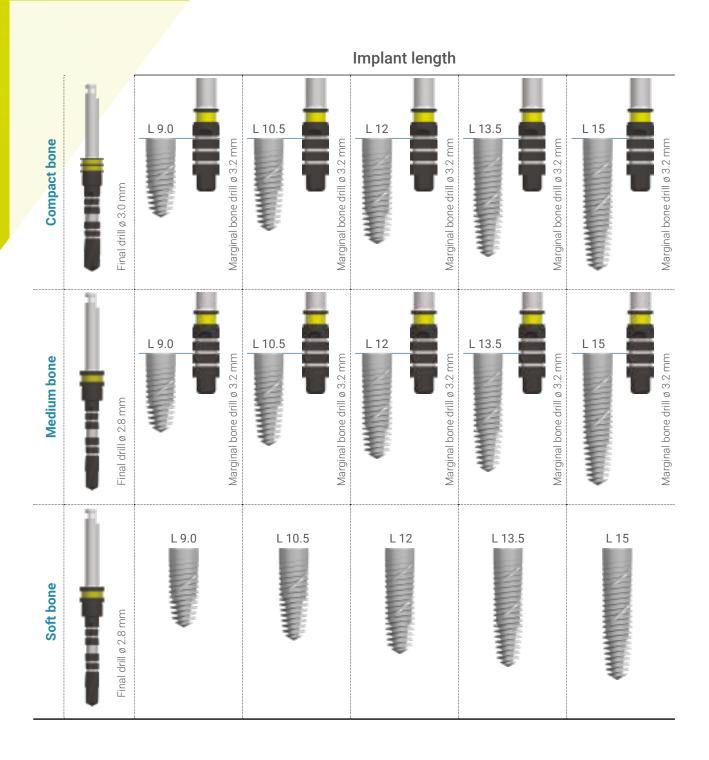
General indications

1	Check that all necessary instruments are available and in perfect working condition. It is advisable to keep an adequate stock of implants and sterile spare instruments available.
2	Do not use cutting instruments more than 10 times on compact bones and more than 50 times on medium bones.
3	Ensure proper cooling of drills with pre-cooled (5°C/41°F) sterile saline solution (NaCl) or Ringer's solution.
4	Do not exceed the speed indications for drills 200-300 rpm.
5	Use drills in ascending order of their diameter and avoid considerable diameter changes when drilling compact bone (always use drills of intermediate diameter in compact bone).
6	Apply only light pressure and an intermittent milling technique (or 'to and fro' movement).



GTB T-ZERO Narrow Ø 3.3 mm Final drills



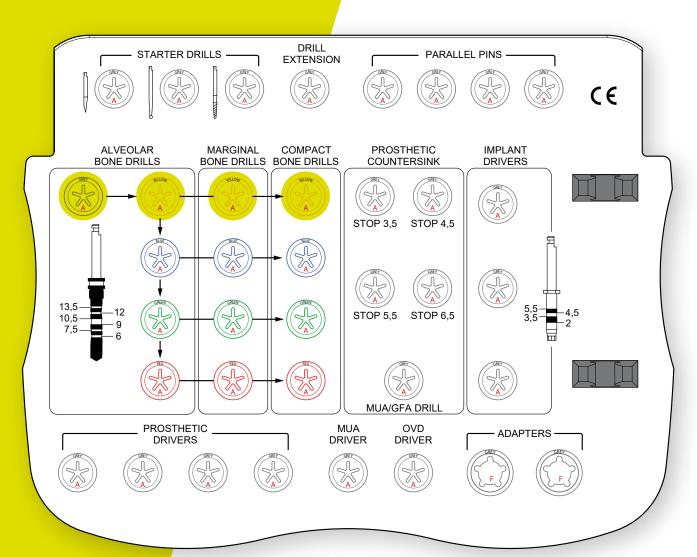


Drill sequence GTB T-ZERO Narrow

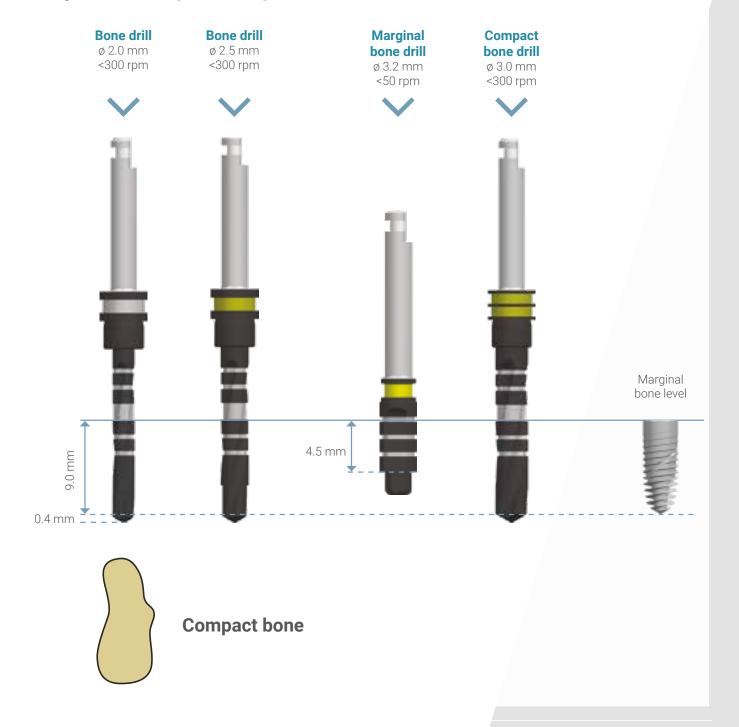




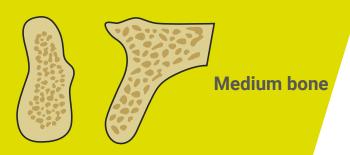
Compact bone

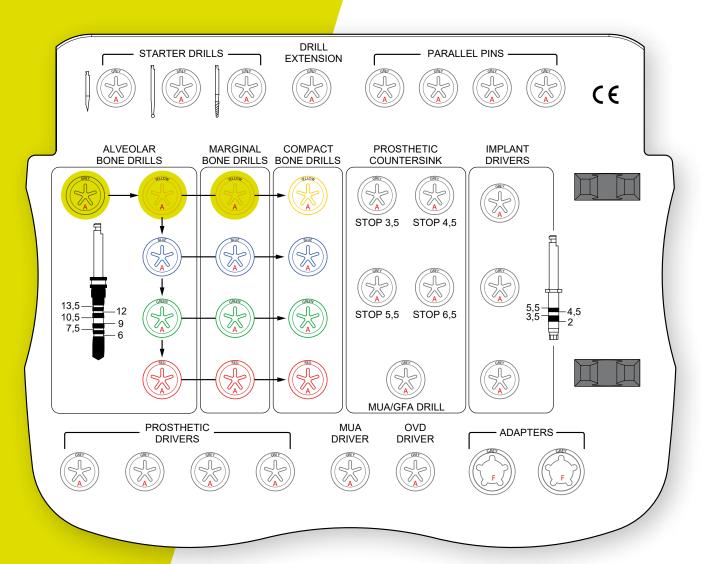


Example for L 9.0 mm length implant and juxta-crestal positioning

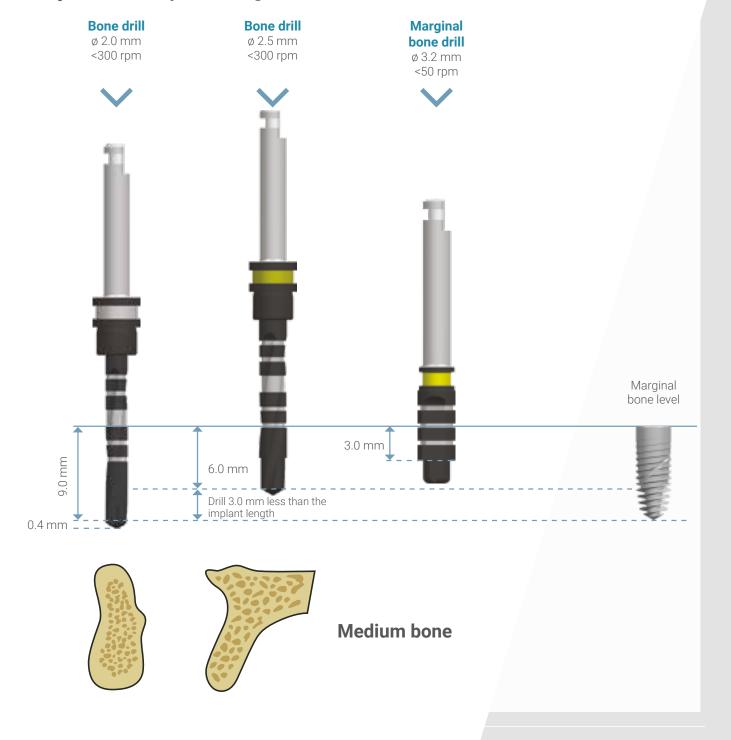


Drill sequence GTB T-ZERO Narrow



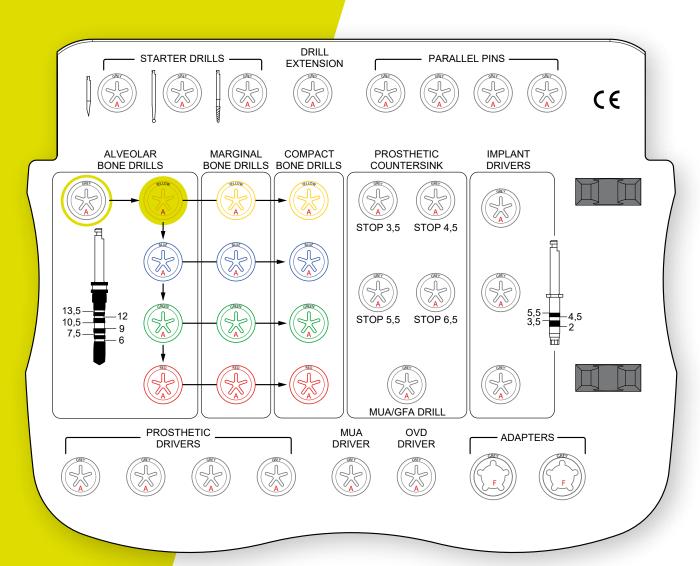


Example for L 9.0 mm length implant and juxta-crestal positioning

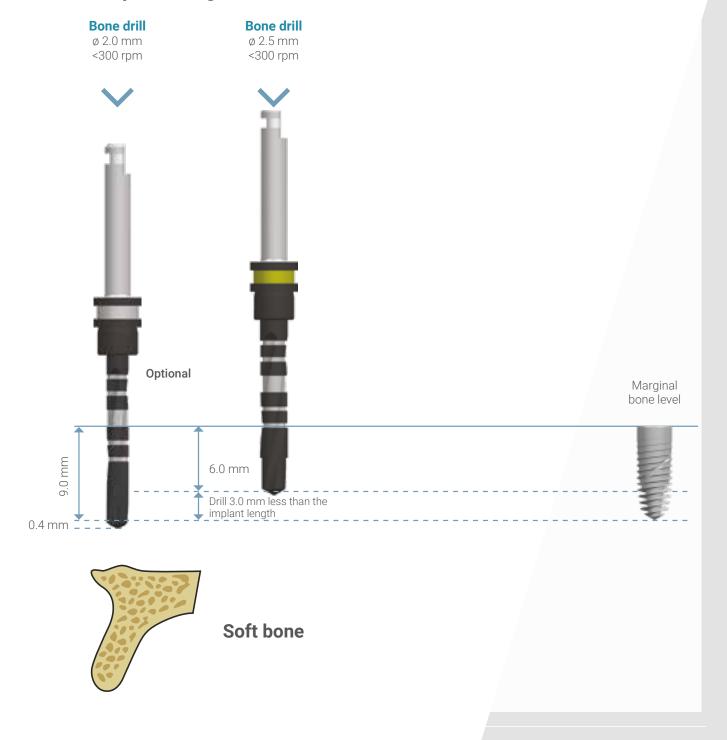




Soft bone

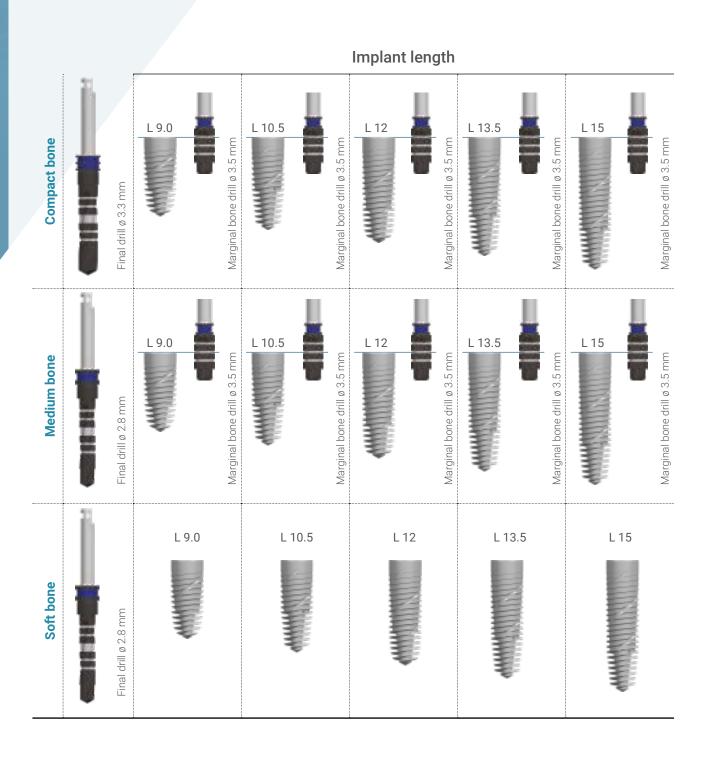


Example for L 9.0 mm length implant and juxtacrestal positioning



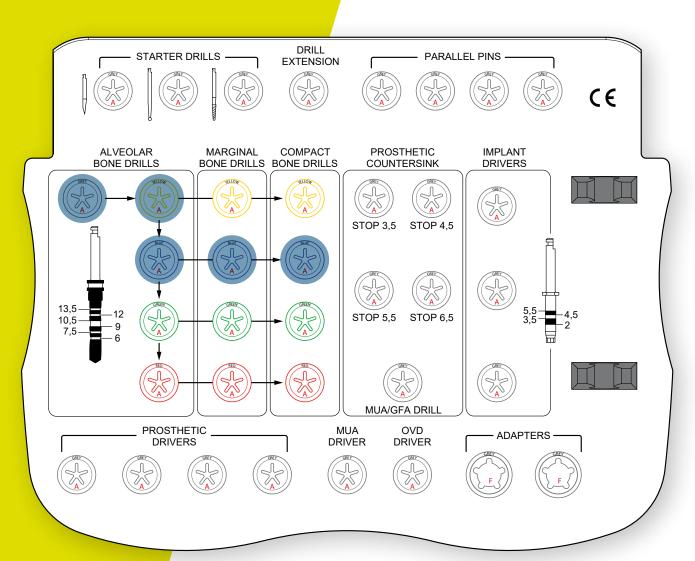
Final drills GTB T-ZERO Regular Ø 3.6 mm







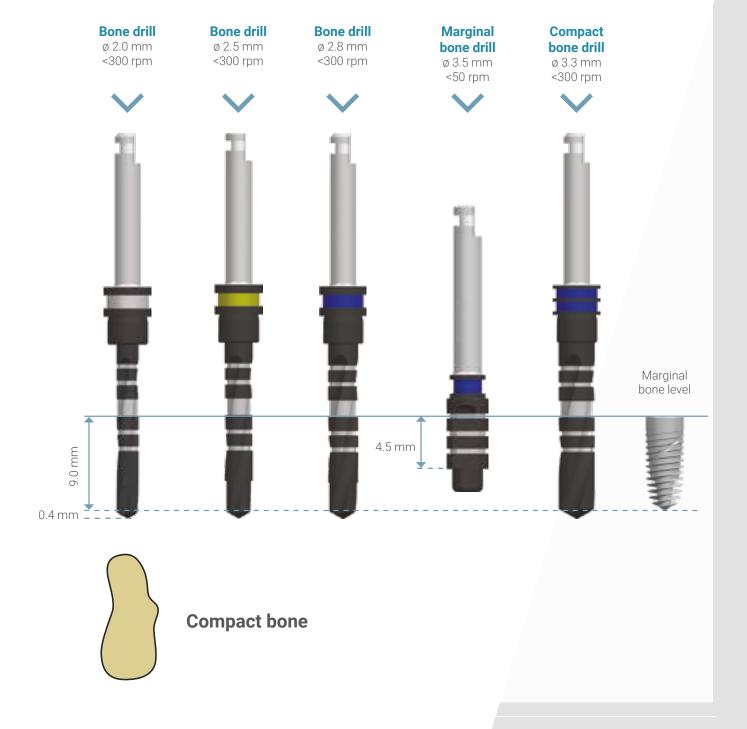
Compact bone

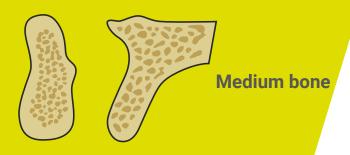


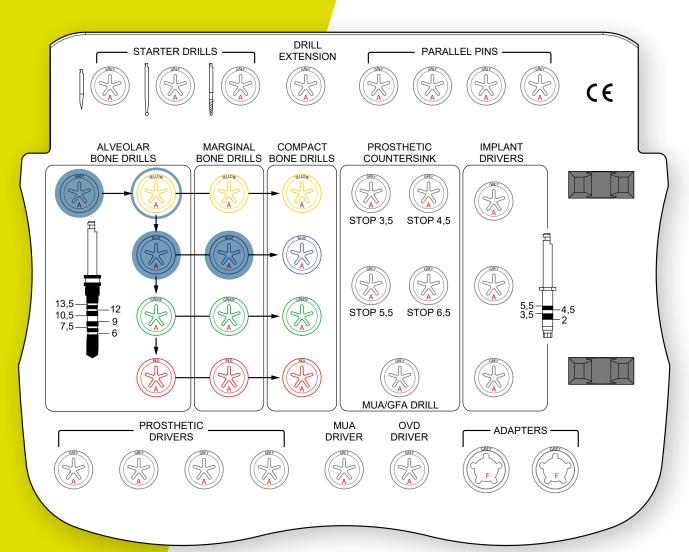
Drill sequence GTB T-ZERO Regular

Ø 3.6 mm

Example for L 9.0 mm length implant and juxta-crestal positioning





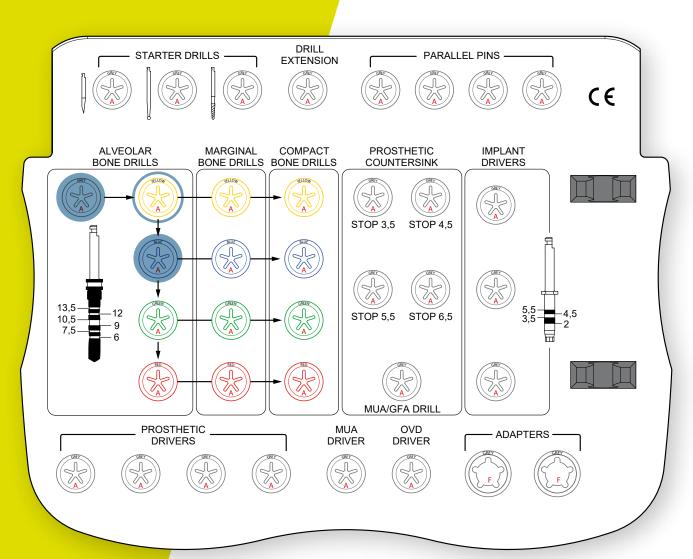


Example for L 9.0 mm length implant and juxta-crestal positioning





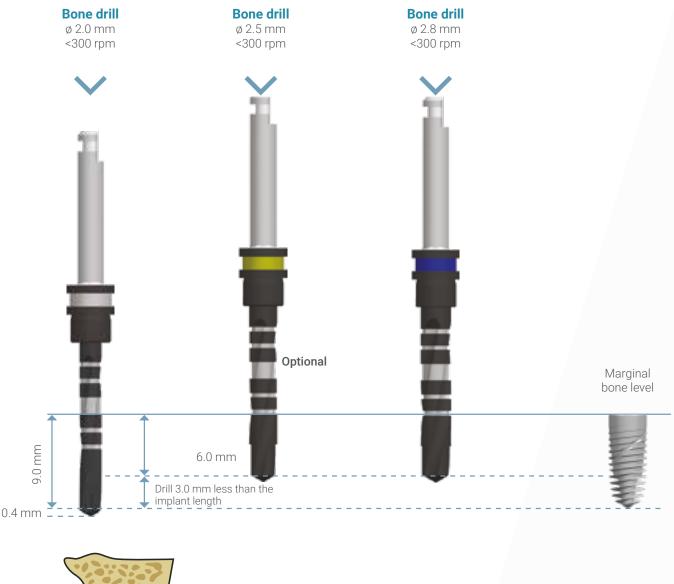
Soft bone



ADVAN Implantology Reinvented

Drill sequence GTB T-ZERO Regular Ø 3.6 mm

Example for L 9.0 mm length implant and juxta-crestal positioning

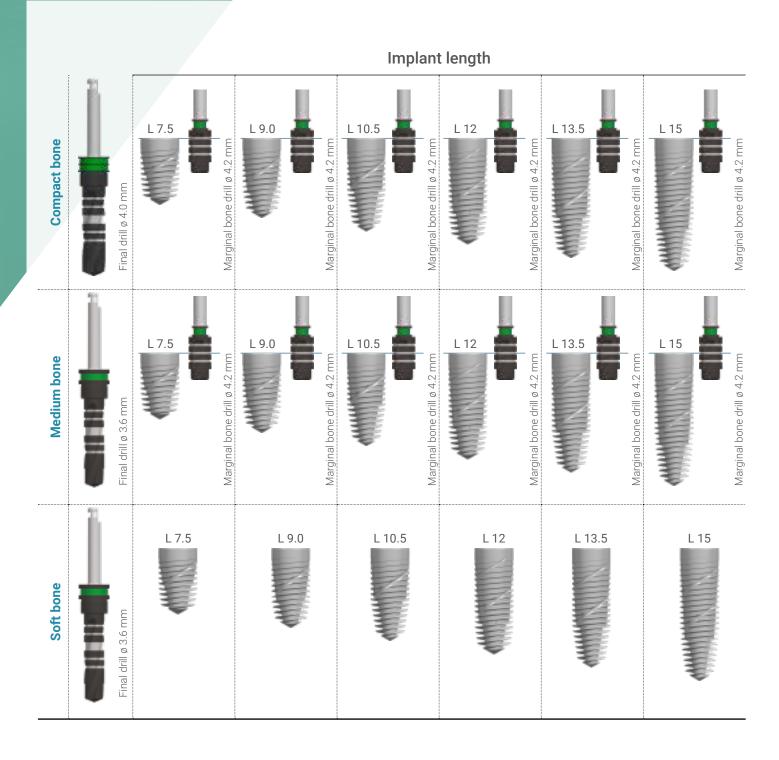




Soft bone

Final drills GTB T-ZERO Wide Ø 4.3 mm



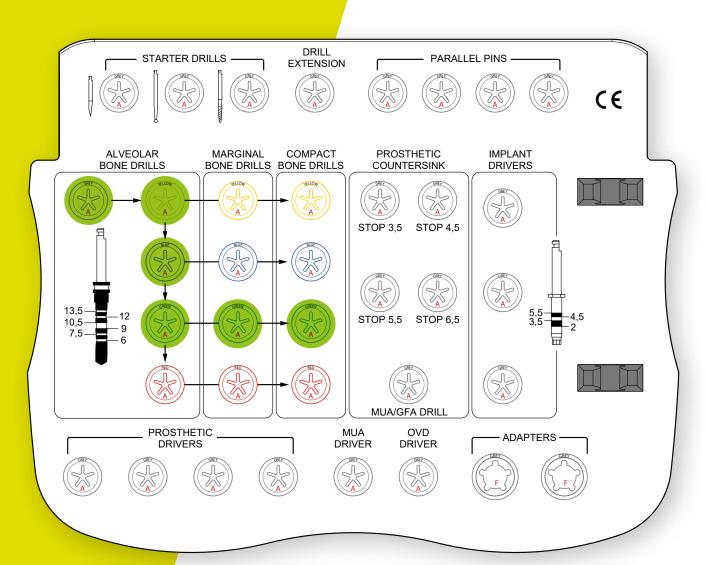


Drill sequence GTB T-ZERO Wide

Ø 4.3 mm



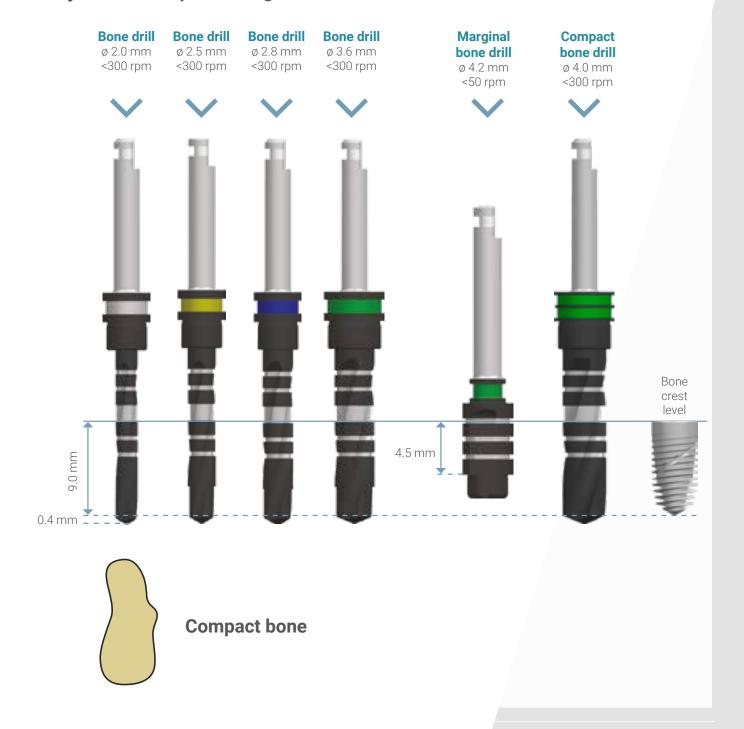
Compact bone





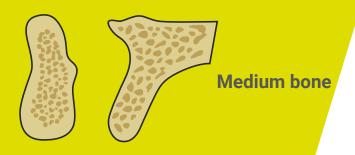
Drill sequence GTB T-ZERO Wide Ø 4.3 mm

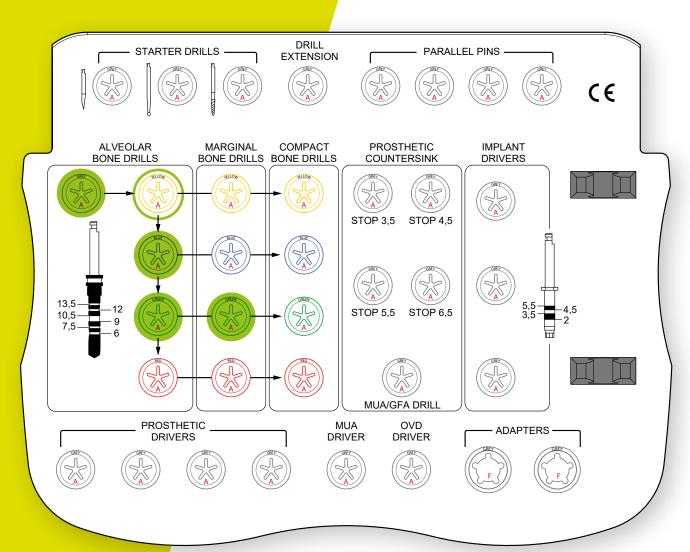
Example for L 9.0 mm length implant and juxta-crestal positioning



Drill sequence GTB T-ZERO Wide

Ø 4.3 mm

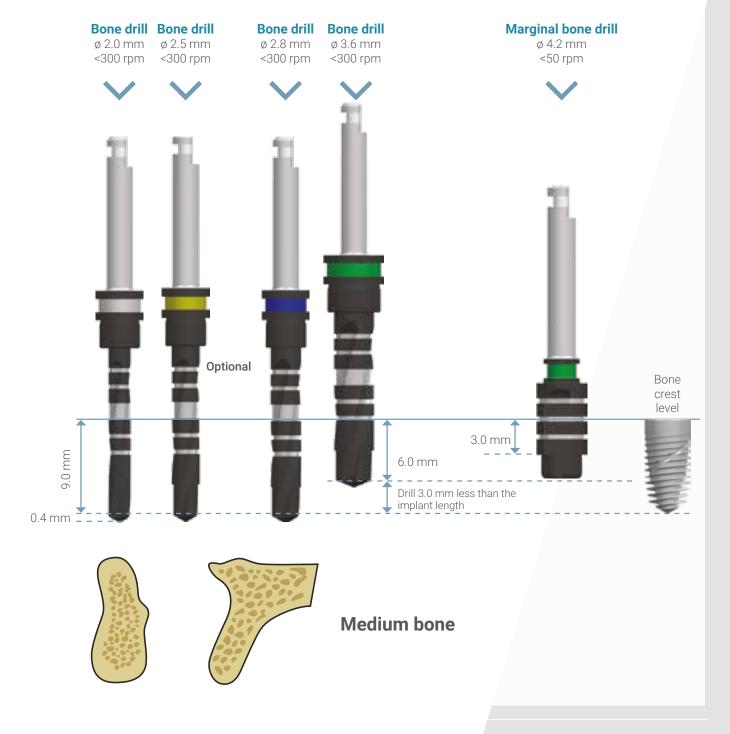






Drill sequence GTB T-ZERO Wide A 3 mm

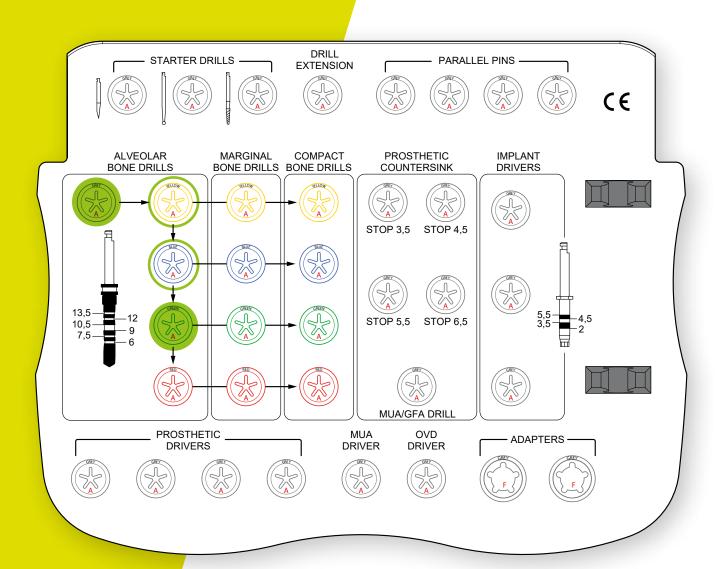
Example for L 9.0 mm length implant and juxta-crestal positioning



Drill sequence GTB T-ZERO Wide

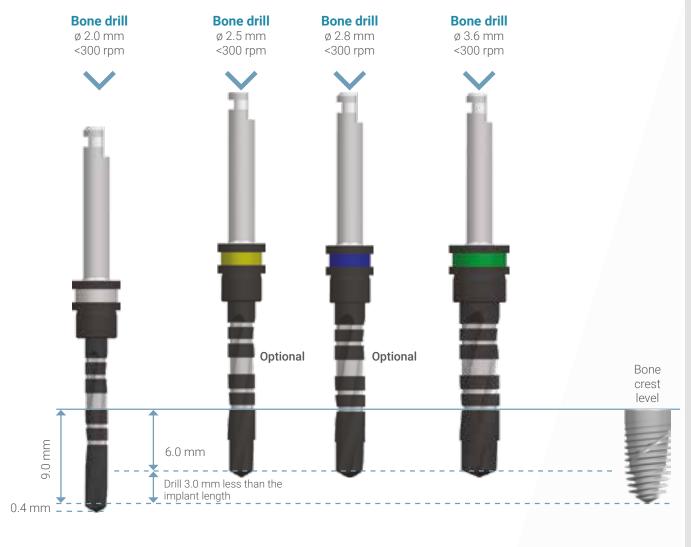


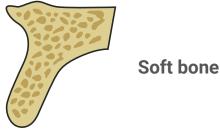
Soft bone



Drill sequence GTB T-ZERO Wide _ADVAN

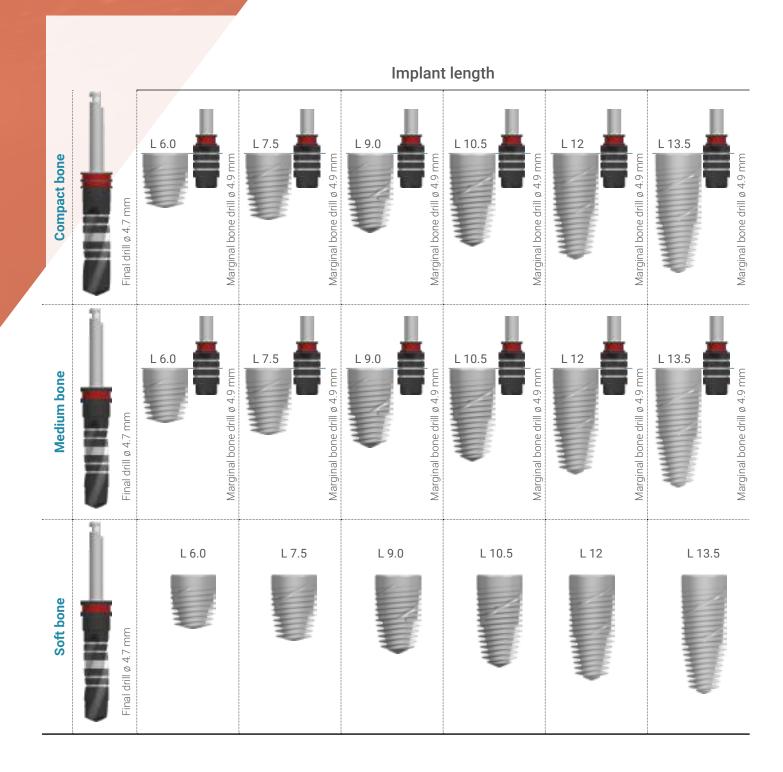
Example for L 9.0 mm length implant and juxta-crestal positioning





Final drills GTB T-ZERO Extra Ø 5.0 mm

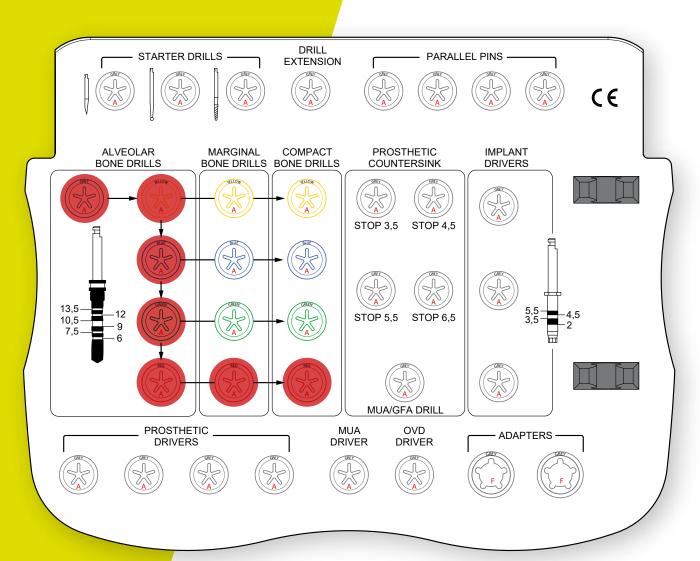




Drill sequence GTB T-ZERO Extra Ø 5.0 mm



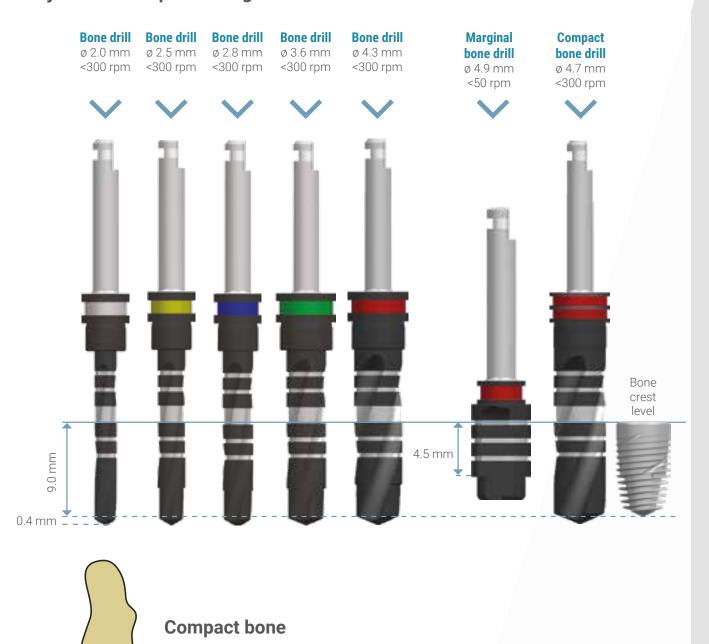
Compact bone



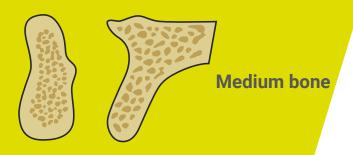
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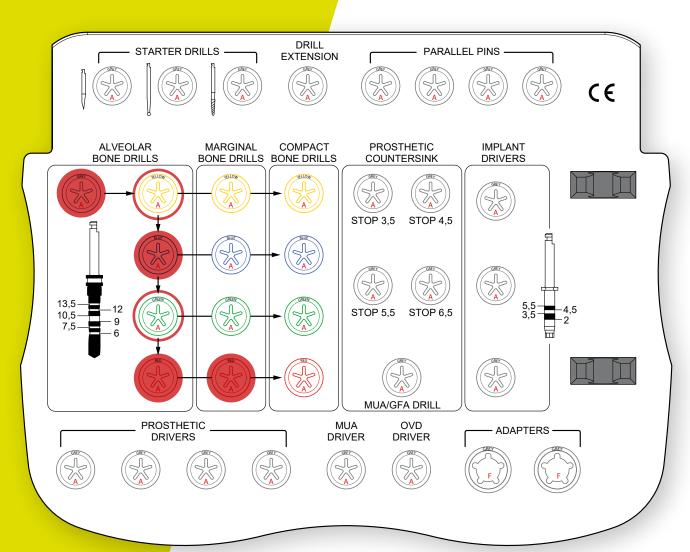
Drill sequence GTB T-ZERO Extra

Example for L 9.0 mm length implant and juxta-crestal positioning



Drill sequence GTB T-ZERO Extra Ø 5.0 mm

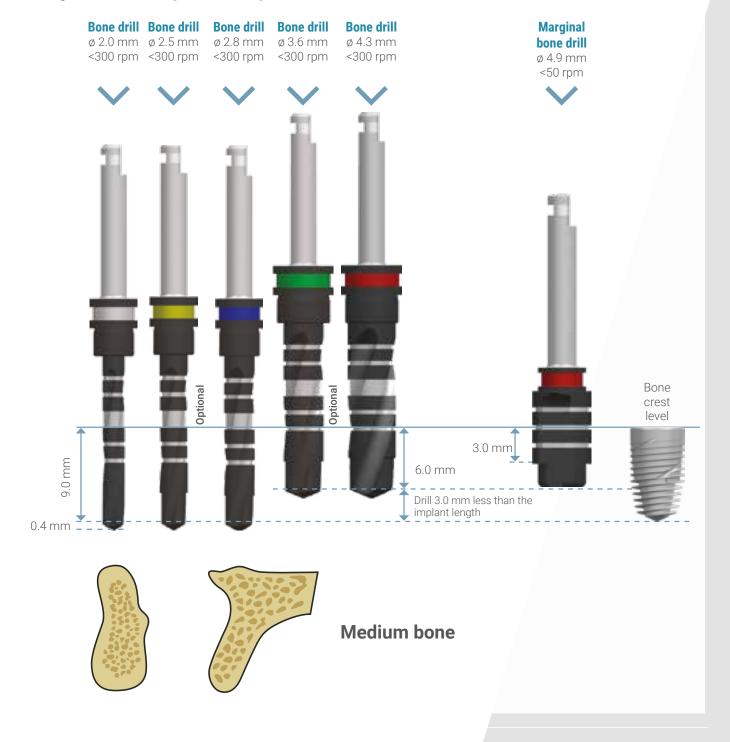




ADVAN

Drill sequence GTB T-ZERO Extra

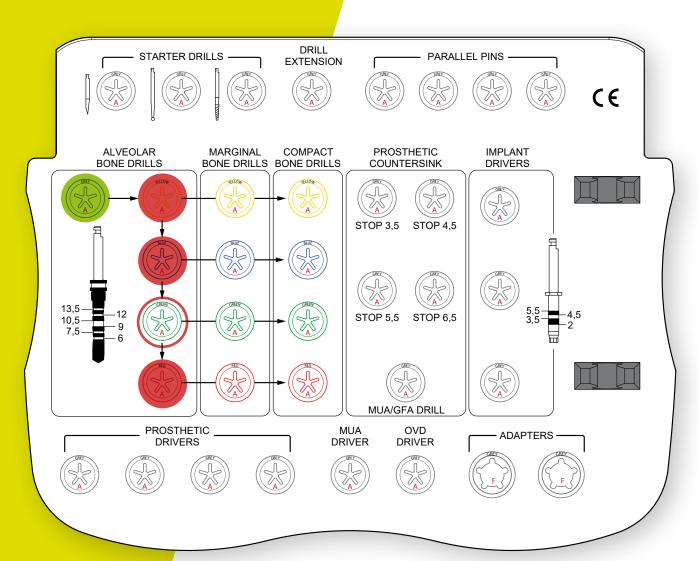
Example for L 9.0 mm length implant and juxta-crestal positioning



Drill sequence GTB T-ZERO Extra Ø 5.0 mm

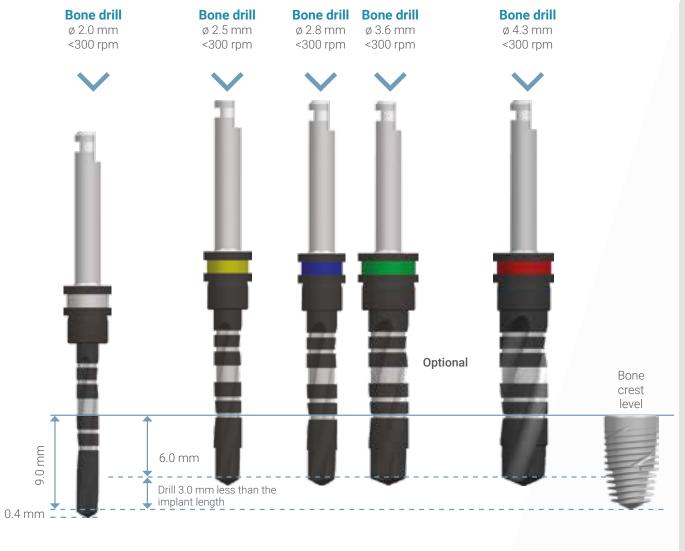


Soft bone



Drill sequence GTB T-ZERO Extra ADVAN

Example for L 9.0 mm length implant and juxta-crestal positioning





Soft bone

Healing phase description

Find some general indications in the table below, keeping in mind, however, that the time for implant recovery and loading should be evaluated separately for each clinical case.

TABLE OF IMPLANT RECOVERY TIMES		
SITUATION	HEALING PHASE DURATION	
 Good bone quality and adequate bone quantity Implants with a diameter of 3.6 mm or 4.3 mm Implants with length of 9 mm or more 	4-6 weeks	
 Poor bone quality or excessively compact bone with poor vascularisation Implants with a diameter of 3.3 mm Implants with length of 6.0 mm or 7.5 mm 	8-12 weeks	
 Implant positioned without adequate primary stability Implant positioned simultaneously to bone restoration procedure Implant positioned simultaneously to considerable sinus elevation 	24-32 weeks	

(Buser, 2000); (European Workshop Consensus Report, 2019); (EAO Consensus Conference, 2021).

Healing phase description

IMMEDIATE PROSTHETIZATION OF IMPLANTS

Unless there are contraindications to consider, all GTB implants are suitable for immediate restoration of a single missing tooth, as well as for restoration of edentulous or partially edentulous mandible.

The essential conditions that must be met: good primary stability (final tightening torque at least 40-45 Ncm), adequate bone quality and appropriate occlusal loading.

In case of rehabilitation of multiple tooth applications the implants may be rigidly splinted. In case of overdenture, a minimum of 4 implants with at least 3.6 mm diameter should be connected together by means of a bar.

Restoration or immediate loading of a single implant has not been studied and is not recommended in the following indications:

- Terminal molar in the mandible and/or the maxilla.
- Cantilevering of a single implant.

PROSTHETISATION OF POST-EXTRACTION IMPLANTS

Appropriate timing for functional loading of post-extraction implants must abide by the same guidelines given above. If the conditions for immediate loading are met and the post-extraction implant is in contact with the 4 walls of the implant site, it is possible to consider the option of immediate loading. If this is not the case, either because there are just 3 walls or because the implant is positioned far palatally, it is recommended to observe approximately 8-12 weeks recovery time. Using the GTB implants, a palatal positioning of the implant is advised.

In case of immediate loading, it is recommended to make a temporary crown out of occlusion, without distalizing or centric contacts, and without contacts in eccentric movements.

IMMEDIATE PROSTHETIZATION OF IMPLANTS

In cases of single or partial edentulias, immediate loading is recommended in anterior regions avoiding the canine pillar, using a temporary crown outside occlusion, without distalizing or centric contacts, and without contacts in eccentric movements.

In case of complete edentulias, the following recommendations apply:

- Minimum 4 implants in the mandible
- Minimum 6 implants in the maxilla
- No particular inclination in mesio-distal and vestibular-lingual directions are required for the implants since the internal vertical conical connection provides optimal support to the prosthetic elements

- It is possible to place short implants of reduced diameter (L6.0 D3.6) in the extraforaminal position
- The short implants with reduced diameter allow to use either a screwed or a cemented prosthesis
- Immediate load must be applied by directly inserting the final prosthesis on a stabilizing bar
- Thanks to the bar-stabilized prosthesis, the conditions for immediate loading must not necessarily be met by all of the implants but at least by 75% of all implants (at least 3 out of 4 implants in the mandible and at least 5 out of 6 implants in the maxilla)

(Buser, 2000); (European Workshop Consensus Report, 2019); (EAO Consensus Conference, 2021).

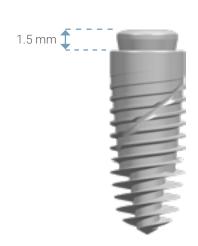
Description of surgical cover screws

The GTB system allows to choose between juxta-crestal and sub-crestal positioning of the implant platform. The surgical cover screw, lodged inside the cap of the implant vial, emerges form the implant platform for about 1.5 mm to guarantee easy implant uncovering in case of two-stage surgery and to allow implant-prosthetic connection without recurring to marginal bone osteotomy (as it is not necessary to free the platform from bone overgrowth).

In case of significant sub-crestal positioning, it is possible to use the membrane cover screw instead of the standard one.

The membrane cover screw is designed for use in guided bone regeneration to crate a curtain with the membrane to provide space for synthetic bone and bone regrowth.

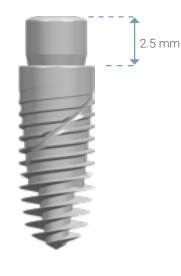
In case of juxta-crestal positioning and a thin gingival biotype, it is possible to use a platform-level cover screw that does not increase the height of the implant platform.



Standard cover screw (included in the GTB implant package code 01GVT01)



Optional cover screw code 01GVT02



Optional cover screw code 01GVT03



Soft tissue management

The aesthetic results largely depend on the successful management of the soft tissues. In order to optimize this process, all GTB prosthetic components are based on the concept of reducing the volume of abutment trans-mucosal pathway (immediately from its emergence at the prosthetic platform level) and using a concave emergence profile of trans-mucosal pathway. This concept is applied to all the healing prosthetic components as well as the prosthetic components for temporary and final reconstruction.

Therefore, the emergence profiles are uniform throughout the entire management process.

Only a slim and concave profile guarantees the required space for peri-implant soft tissue which will thus remains stable over the time and enable to easily achieve excellent aesthetic results.

It is now common knowledge that the "One Time Abutment" prosthetic protocols, if performed with innovative implant systems such as the GTB, allow for superior and longer-lasting biological and aesthetic results. Obviously, it is possible to use different methods to adapt the implant system to specific requirements of each clinical case.

After insertion, the implant is closed (hand-tightened; see

the tightening torque table on page 69) and protected with a cover screw, a healing abutment or a prosthetic abutment (in case of immediate loading protocol). The surgeon can choose between sub-mucosal and trans-mucosal healing and, thanks to an ingeniously designed series of prosthetic healing components, can avail of all existing options for soft tissue management.

The non-epithelialized side of the flap should be approximated to the implant neck (soft tissue adaptation).

If necessary, this step must be combined with a gingivectomy. The wound margins are closed with atraumatic suture material, and the sutures must not be tied too tightly. One relieving suture is placed on either side of the cover screw or the healing abutment so that the wound margins are approximated without tension.

Use of non-absorbable suture material is recommended (e.g. Polyamide or Teflon).

The sutures are removed in 7–10 days.

A post-operative radiographic control is advised.

Prosthetic components tightening torque

The tightening torque of the prosthetic components plays a fundamental role in vertical connection implant systems with coupling cone. The torque must, in fact, be calibrated to activate the connection and allow the removal of the prosthetic component at the same time.

In case of conical coupling connection, the retention screw serves to activate the conical surface of the connection itself. For this reason, a minimum and a maximum torque will always be indicated. The minimum torque indicates the value above which the conical connection of the implant system is activated (reference value during the temporary prosthetic rehabilitation phase) whereas the maximum torque indicates the maximum value at which to tighten the retention screw (reference value during the final prosthetic rehabilitation).

Some of the prosthetic components, i.e. cover screws, healing abutments and transfer abutments, have a reduced coupling cone to facilitate the removal of a temporary element, yet still granting the perfect closure of the implant-abutment connection characterising the GBT implant system (a very important aspect when using cover screws and healing abutments).

In case of One Time Abutment technique, it is advised to tighten the abutment with 15 Ncm torque during temporary phase and then increase it to 20-25 Ncm before cementing the final crown (leaving the abutment in place).



RECOMMENDED TIGHTENING TORQUES		
V	Cover screw	7 Ncm MAX
	Transfer abutment	7 Ncm MAX
V	Healing abutment	7 Ncm MAX
	Abutment in temporary phase	15 Ncm
	Abutment in final phase	25 Ncm
	Gingival Former Abutment	35 Ncm

Cleaning and maintenance of the surgical kit

RECONDITIONING INSTRUCTIONS

After the surgical procedure, all instruments are contaminated due to contact with blood, saliva and potentially infected organic substances. Therefore, all instruments must be properly cleaned, disinfected and sterilised before each use.

Initial treatment after use:

Immediately after use, or no more than 30 minutes after use, remove coarse dirt with absorbent paper towels.

Containment and transport:

It is recommended to recondition instruments as soon as reasonably possible after use, or at the latest within 30 minutes after use. To avoid mechanical damage, do not mix heavy devices with delicate ones. Pay special attention to the drill cutting edges.

Preparation before cleaning:

Disassemble the instruments if they consist of several parts. Disassemble the kit in its entirety.

Manual cleaning:

- Immediately after use, or at the latest within 30 minutes after use, place the instruments in a suitable solution of high quality enzymatic detergent (ENZYMAX®, 0.8% v/v with demineralised water) at 35°C contained in a suitable holder (e.g. Becker); the instruments must be totally covered by the solution. Wait 10 minutes before removing them. Take care that the instruments do not come into contact with each other.
- Using a soft plastic brush (e.g. soft nylon brush), clean each instrument thoroughly to remove any organic residue.

Warning: Do not use brushes on retention systems.
Warning: do not clean instruments with wire brushes or steel wool.

- 3. Rinse instruments thoroughly under running or distilled water to remove all traces of detergent (e.g. enzymatic).
- 4. Place the instruments in a solution as described in step 1 inside a suitable holder (e.g. beaker), place the holder in an ultrasonic washing machine for 10 minutes at 35°C. Note: Instruments must be properly positioned to avoid collisions between instruments and the container itself; suitable holders (e.g. beakers) are recommended.
- 5. Rinse instruments thoroughly under running or distilled water to remove all traces of detergent (e.g. enzymatic). Warning: prolonged immersion times and/or excessive concentration of solution can cause corrosion of instruments; always follow the recommendations for immersion time provided by the solution manufacturer.

Manual disinfection:

Immediately after manual cleaning, or within 30 minutes at the latest, place the instruments in a high quality disinfectant solution (PROSEPT® Burs, ready-to-use solution), contained in a suitable holder (e.g. beaker); the instruments must be completely covered by the solution. Place the holder in an ultrasonic washing machine for 1 minute at 20°C before removing it. Take care that the instruments do not come into contact with each other.

Warning: To avoid corrosion, do not rinse rotating instruments with water during this reconditioning phase.

Automatic cleaning/disinfection: Not applicable.

Drying:

Dry each instrument thoroughly with compressed air (max. 2 bar) using only filtered air (oil-free and low in contamination of microorganisms and particles). The presence of moisture on the surface of instruments can promote bacterial growth and compromise the sterilisation process. Drying the instruments is of utmost importance before storage and sterilisation,



because moisture accumulation on products is harmful and can cause oxidation.

Maintenance:

At the end of each cleaning, disinfection and drying cycle, the instruments must be visually checked to ensure that they are macroscopically clean. Damaged instruments must be removed to avoid the reuse of blunt or damaged instruments. This visual check is absolutely essential for any instrument that affects the result of the operation. An instrument that is not sharp, or is corroded or contaminated can damage or infect healthy tissue.

Notes: Visual inspection is as important as cleaning, disinfection, drying and sterilisation.

Instruments that are not completely clean must undergo another cleaning, disinfection and drying cycle. Damaged instruments must always be removed.

Inspection and operation: It is recommended that surgical instruments are frequently checked for wear and tear and that worn-out instruments are replaced immediately. In particular:

- 1. cutting tools: it is very important to check cutting performance before each use; replace those tools that cannot guarantee adequate cutting performance, leading to inaccurate cutting and overheating of the bone. It is recommended not to use them more than 10 times on hard bone and no more than 50 times on medium/soft bone;
- 2. Instrument coupling parts: instrument parts that are mechanically coupled are subject to wear and tear (screwdrivers, handpiece instruments, drill extensions, handpiece couplings). It is recommended that after each cleaning, disinfection and sterilisation cycle, the retention systems of implant screwdrivers should be checked for wear and tear and those that may no longer ensure proper retention should be replaced;
- 3. It is recommended that calibrated instruments be periodically checked for proper functioning (e.g. torque spanner).

Packaging: Place the instruments back in the appropriate slot inside the surgical tray. The surgical kit must be placed in a sterilisation pouch that meets the following requirements: EN ISO 11607 (e.g. medical paper); suitable for steam sterilisation; sufficient protection for instruments and to avoid damage to sterilisation packaging (the pouch protects the kit during sterilisation and keeps it sterile until the next use).

Pack the surgical kit with the sterilisation pouch and place it inside the autoclave in a horizontal position; do not turn it upside down to ensure proper drying.

STERILISATION

The instruments are reusable and supplied in non-sterile condition, being individually packaged. These devices must be properly cleaned, disinfected and sterilised before each use.

Warning: Do not autoclave this device in its original packaging.

For steam sterilisation of the surgical kit we recommend the use of an autoclave which meets the following requirements: EN ISO 17665. Carefully adhere to the instructions and recommendations of the autoclave manufacturer. Follow the instructions for maintenance and calibration of the autoclave. It was validated that a steam sterilisation cycle at 134°C, 4 minutes, 2 bar and 1 hour total duration, resulted in sterilization of the surgical kit; this condition was certified by an accredited laboratory.

If not already present on the sterilization pouch, it is recommended to place a chemical indicator inside the autoclave during the process to confirm sterilization effectiveness.

It is recommended to sterilize the instruments arranged in the appropriate position inside the surgical tray. Pack the surgical tray with sterilization pouch and put it inside the autoclave in a horizontal position; do not turn it upside down to ensure the proper drying.

Notes: Users must ensure that the sterilizer and all sterilization accessories (sterilization sheets, envelopes, sterilization trays, biological and chemical indicators) are correctly calibrated and approved for the intended sterilization cycle. If there are visible signs of humidity (damp spots on the sterile package, stagnant water in the load) at the end of the sterilization cycle, repackage and re-sterilize.

When removing the instruments from the sterile package, follow the aseptic principles. The sterile packaging must not be opened until immediately before the use of the instrument. Instruments with damaged sterile packaging should not be used. It is advisable to keep a replacement instrument on hand.

STORAGE

Store in dark, cool and dry place. It is recommended to keep the pouch closed until next surgical procedure.

Follow the instructions of the manufacturer of the pouches regarding storage conditions and expiration date of sterilized goods.

Cleaning and maintenance of the surgical kit

FURTHER INFORMATION

Advan surgical instruments are made of materials suitable for surgical use and for severe conditions occurring during cleaning, disinfection and sterilization. We recommend not to exceed with disinfection and sterilization processes (disinfectant concentrations, temperatures, times, etc.) since it may reduce instrument lifetime. We recommend to follow the manufacturer's instructions for all products used in combination with Advan surgical instruments.

Instruments that have not been used must be, in any case, washed and sterilized before the next use; new instruments provided in original packaging by Advan must be washed and sterilized before use.

The instructions provided above have been validated by the manufacturer of the medical devices to be capable of preparing a medical device for reuse. It remains the responsibility of the user to ensure that the reprocessing, as actually performed using equipment and materials available in the reprocessing facility, achieved the desired result. This normally requires verification and/or validation and routine monitoring of the process.

For more information on the use of Advan products, contact Advan customer service.

DISPOSAL

Disposal must be managed in an environmentally sustainable way, in compliance with local regulations. Hazardous waste from contaminated devices or sharp objects must be disposed of in suitable containers that meet specific technical requirements.

LIFECYCLE

The Advan Kit is recommended for up to 50 uses, as long as

the conditions of use indicated by Advan are respected. With regards to the cutting tool lifecycle, please refer to paragraph inspection and function point 1. Anyway, regardless of the number of times that the instrument has been used, the professional should always evaluate its condition after each use.

NOTES

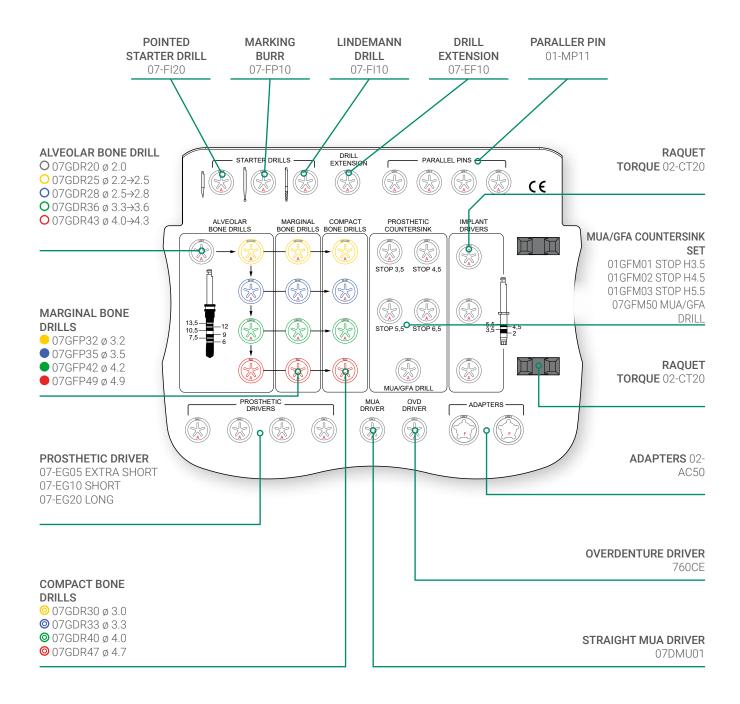
Doctors who use the Advan product are required to have appropriate technical knowledge and training, in order to ensure its safe use. Advan devices must be used in accordance with the instructions for use provided by the manufacturer. The doctor is responsible for the use of the device in accordance with these instructions for use and for determining the suitability of the device for the individual patient situation. The Advan Product is part of a complete program and must only be used in conjunction with its original components and instruments distributed directly by Advan and all Advan national dealers. The use of third part products not distributed by Advan voids any warranty or other obligation, implicit or explicit, of Advan.







Maintenance of the surgical kit





THE FIRST HIGH BIOLOGICAL PERFORMANCE IMPLANT SYSTEM

Guidelines Surgical



Advan Implantology Via Rosta della Maina, 2 33020 Amaro (UD) Tel. (+39) 0433.096245 email: info@advanimplantology.com

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