SURGICAL PROCEDURE

GALAXY 3D

Surgical procedure for Galaxy implants

Ziacom®

GALAXY 3D

Surgical procedure for Galaxy implants

Ziacom®

Important information

Please read carefully before using Ziacom® products

General information

This document contains basic information on the use of original Ziacom® dental implant systems, hereafter referred to as "Ziacom® dental implants" or simply "Ziacom® products". This document has been created as a quick guide for clinicians responsible for treatment, hereafter the "user", and therefore, is neither an alternative nor a substitute for specialised training or professional clinical experience.

Ziacom® products must be used according to a suitable treatment plan and in strict compliance with the manufacturer's surgical and prosthetic protocols. Carefully read the product-specific surgical and prosthetic protocols and the instructions for use and maintenance before using any Ziacom® product. You can find this information on our website, www.ziacom.com, or request it from your nearest authorised Ziacom® distributor.

Liability, safety and warranty

The instructions for the use and handling of Ziacom® products are based on internationally published literature, current clinical standards and our clinical experience so they should be understood as general guidance. The handling and use of Ziacom® products is the sole responsibility of the user as it is outside the control of Ziacom Medical SL. Ziacom Medical SL, its subsidiaries and/or its authorised distributors disclaim all responsibility, whether explicit or implicit, total or partial, for possible damage or injury caused by poor handling of the product or any other situation not considered in their protocols and manuals for the correct use of their products.

The user must ensure that the Ziacom® product is appropriate for the intended procedure and end purpose. Neither these instructions for use nor the work or handling protocols for the products release the user from this obligation. Ziacom® products must be used, handled and applied by clinicians with the appropriate training and qualifications required according to current legislation in each country.

The total or partial use, handling and/or application of Ziacom® products at any stage of their implementation by personnel who are unqualified or lack the necessary training will automatically void any type of warranty and may cause severe damage to the patient's health.

Ziacom® products are part of their own system, with their own design characteristics and work protocols, including dental implants, abutments or prosthetic components and surgical or prosthetic instruments. The use of Ziacom® products in combination with elements or components from other manufacturers could result in treatment failure, damage to tissues or bone structures, inadequate aesthetic outcomes and severe damage to the patient's health. Therefore, only original Ziacom® products should be used.

The clinician in charge of the treatment is solely responsible for ensuring the use of original Ziacom® products and that they are used according to the corresponding instructions for use and handling protocols throughout the implant procedure. The use of any other non-original Ziacom® components, instruments or products, whether alone or in combination with any original Ziacom® products, will immediately void the warranty of the original Ziacom® products.

See the Ziacom Medical SL Warranty Programme (available on the website or by contacting Ziacom Medical SL, its subsidiaries or authorised distributors).

Warning. Not all Ziacom® products are available in all counties. Check availability in your country.

Together for **health**

Table of contents

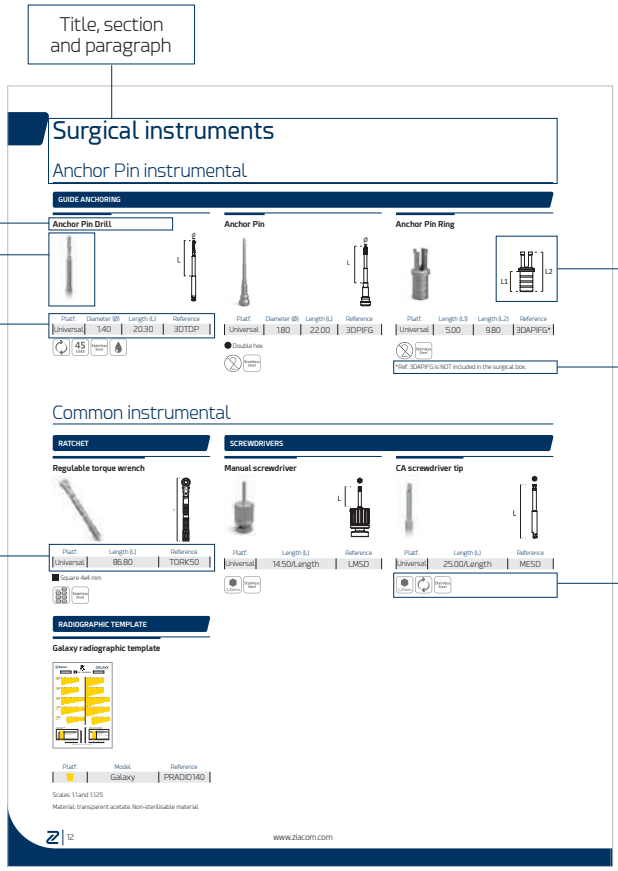
Galaxy 3D | Surgical procedure for guided surgery


GALAXY 3D

Surgical instruments

How to use this catalogue

Product data sheet



Symbology

Symbol	Meaning
ROT	Rotatory element
NO ROT	Non-rotatory element
	Use with manual torque
XX Ncm	Maximum operating torque
Ncm 10 20 30 40 50 60 70	Ratchet torque range
Galaxy	Galaxy connection
1,25mm	Screw connection
Kirator	Kirator connection
N Nature	Nature connection
Basic	Basic connection
XDrive	XDrive connection

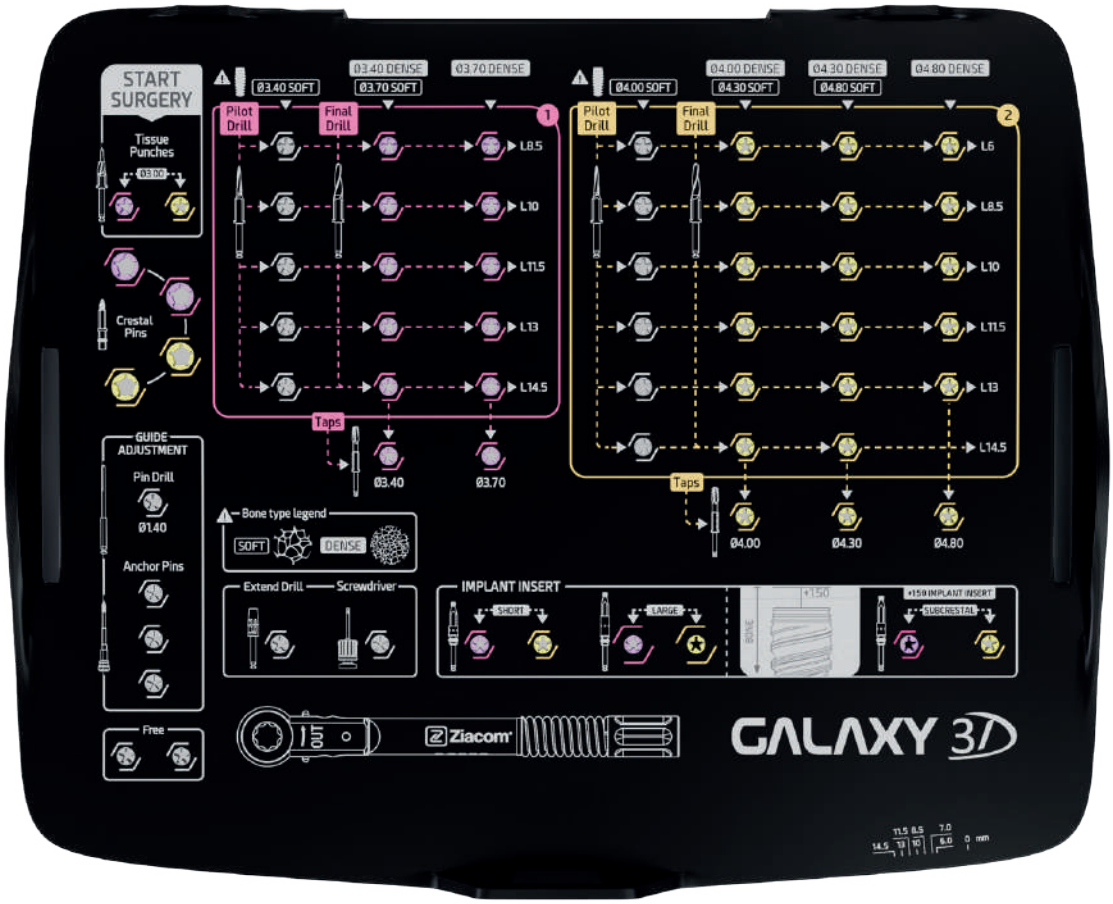
Symbol	Meaning
	Tx30 connection
MX,XX	Size in millimetres
45°	45° screw support
90°	90° screw support
	Use in rotation with a CA
XX Rpm	Maximum rotation speed
XX USES	Maximum number of uses
	Single-use product
Grade 5 ELI Titanium	Made from grade 5 ELI (extra-low interstitial) titanium
Grade 2 Titanium	Made from grade 2 titanium
Stainless Steel	Made from stainless steel

Symbol	Meaning
Steel	Made from steel
Co-Cr +castable	Made from cobalt-chromium + castable plastic
Cobalt Chromium	Made from cobalt-chromium
PEEK	Made from PEEK
Full castable	Made from castable plastic
Plastic	Made from plastic
XX°	Recommended sterilisation temperature
Non sterile	Unsterilised product
	Use with abundant irrigation
XX°	Maximum angle

GALAXY

Surgical instruments

Surgical box



■ Galaxy 3D contents available

Platf.	Contents	Reference
	Empty	3DBOX901
	Complete	3DBOX901C

134°

Material: Radel.

Ensure boxes do not touch the walls of the autoclave to avoid damage.

Surgical box contents

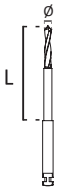
REF	Description	3DBOX901C
3DRPG185	Galaxy 3D Pilot Drill. 1. 8.5 mm.	●
3DRPG110	Galaxy 3D Pilot Drill. 1. 10 mm.	●
3DRPG115	Galaxy 3D Pilot Drill. 1. 11.5 mm.	●
3DRPG113	Galaxy 3D Pilot Drill. 1. 13 mm.	●
3DRPG114	Galaxy 3D Pilot Drill. 1. 14.5 mm.	●
3DTDG3485	Galaxy 3D Surgical Drill. 1. 8.5 mm.	●
3DTDG3410	Galaxy 3D Surgical Drill. 1. 10 mm.	●
3DTDG3415	Galaxy 3D Surgical Drill. 1. 11.5 mm.	●
3DTDG3413	Galaxy 3D Surgical Drill. 1. 13 mm.	●
3DTDG3414	Galaxy 3D Surgical Drill. 1. 14.5 mm.	●
3DTDG3785	Galaxy 3D Surgical Drill. 1. 8.5 mm.	●
3DTDG3710	Galaxy 3D Surgical Drill. 1. 10 mm.	●
3DTDG3715	Galaxy 3D Surgical Drill. 1. 11.5 mm.	●
3DTDG3713	Galaxy 3D Surgical Drill. 1. 13 mm.	●
3DTDG3714	Galaxy 3D Surgical Drill. 1. 14.5 mm.	●
3DRPG206	Galaxy 3D Pilot Drill. 2. 6 mm.	●
3DRPG285	Galaxy 3D Pilot Drill. 2. 8.5 mm.	●
3DRPG210	Galaxy 3D Pilot Drill. 2. 10 mm.	●
3DRPG215	Galaxy 3D Pilot Drill. 2. 11.5 mm.	●
3DRPG213	Galaxy 3D Pilot Drill. 2. 13 mm.	●
3DRPG214	Galaxy 3D Pilot Drill. 2. 14.5 mm.	●
3DTDG3906	Galaxy 3D Surgical Drill. 2. 6 mm.	●
3DTDG3985	Galaxy 3D Surgical Drill. 2. 8.5 mm.	●
3DTDG3910	Galaxy 3D Surgical Drill. 2. 10 mm.	●
3DTDG3915	Galaxy 3D Surgical Drill. 2. 11.5 mm.	●
3DTDG3913	Galaxy 3D Surgical Drill. 2. 13 mm.	●
3DTDG3914	Galaxy 3D Surgical Drill. 2. 14.5 mm.	●
3DTDG4006	Galaxy 3D Surgical Drill. 2. 6 mm.	●
3DTDG4085	Galaxy 3D Surgical Drill. 2. 8.5 mm.	●
3DTDG4010	Galaxy 3D Surgical Drill. 2. 10 mm.	●
3DTDG4015	Galaxy 3D Surgical Drill. 2. 11.5 mm.	●
3DTDG4013	Galaxy 3D Surgical Drill. 2. 13 mm.	●
3DTDG4014	Galaxy 3D Surgical Drill. 2. 14.5 mm.	●
3DTDG4406	Galaxy 3D Surgical Drill. 2. 6 mm.	●
3DTDG4485	Galaxy 3D Surgical Drill. 2. 8.5 mm.	●
3DTDG4410	Galaxy 3D Surgical Drill. 2. 10 mm.	●
3DTDG4415	Galaxy 3D Surgical Drill. 2. 11.5 mm.	●
3DTDG4413	Galaxy 3D Surgical Drill. 2. 13 mm.	●
3DMPTB1	Galaxy 3D Soft Tissue Punch/Crestal Bone Profiler. 1.	●
3DMPTB2	Galaxy 3D Soft Tissue Punch/Crestal Bone Profiler. 2.	●
3DTDP	Zinic® 3D Anchor Pin Drill.	●
3DMTAPG34	Galaxy 3D Surgical Tap. Ø 3.40 mm. Millimeter.	●
3DMTAPG37	Galaxy 3D Surgical Tap. Ø3.70 mm. Millimeter.	●
3DMTAPG40	Galaxy 3D Surgical Tap. Ø4.00 mm. Millimeter.	●
3DMTAPG43	Galaxy 3D Surgical Tap. Ø4.30 mm Millimeter.	●
3DMTAPG48	Galaxy 3D Surgical Tap. Ø4.80 mm. Millimeter.	●
3DPIF1	Galaxy 3D Crestal Anchor Pin. 1. Threaded	●
3DPIF2	Galaxy 3D Crestal Anchor Pin. 2. Threaded	●
3DPIFG	Galaxy 3D Anchor Pin	●
DEXT10	Drill extender	●
LMSD	Surgical screwdriver. 1.25 mm. Long.	●
3DLMRGV1	Galaxy 3D VPress insertion key 1. Long. Millimeter.	●
3DLMRGV2	Galaxy 3D VPress insertion key 2. Long. Millimeter.	●
3DSMRGV1	Galaxy 3D VPress insertion key 1. Short. Millimeter.	●
3DXMRGV1	Galaxy 3D VPress insertion key 1. H1.5mm. Millimeter.	●
3DSMRGV2	Galaxy 3D VPress insertion key 2. Short. Millimeter.	●
3DXMRGV2	Galaxy 3D VPress insertion key 2. H1.5mm. Millimeter.	●
TORK50	Regulable torque wrench	●

Surgical instruments

Anchor Pin instrumental

GUIDE ANCHORING

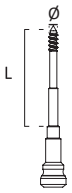
Anchor Pin Drill



Platf.	Diameter (Ø)	Length (L)	Reference
Universal	1.40	20.30	3DTDP

45 USES · Stainless Steel

Anchor Pin

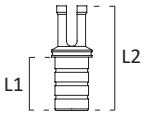


Platf.	Diameter (Ø)	Length (L)	Reference
Universal	1.80	22.00	3DPIFG

● Double hex

Stainless Steel

Anchor Pin Ring



Platf.	Length (L1)	Length (L2)	Reference
Universal	5.00	9.80	3DAPIFG*

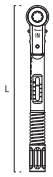
Stainless Steel

*Ref. 3DAPIFG is NOT included in the surgical box.

Common instrumental

RATCHET

Regulable torque wrench



Platf.	Length (L)	Reference
Universal	86.80	TORK50

■ Square 4x4 mm

Ncm 10 20 30 40 50 60 70 · Stainless Steel

SCREWDRIVERS

Manual screwdriver

Platf.	Length (L)	Reference
Universal	14.50/Length	LMSD

1,25mm · Stainless Steel

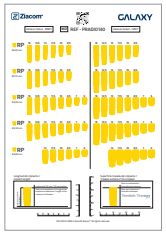
CA screwdriver tip

Platf.	Length (L)	Reference
Universal	25.00/Length	MESD

1,25mm · Stainless Steel

RADIOGRAPHIC TEMPLATE

Galaxy radiographic template



Platf.	Model	Reference
▼	Galaxy	PRADI0140

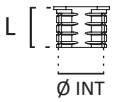
Scales 1:1 and 1:1.25

Material: transparent acetate. Non-sterilisable material

Instrumental for Ø3.40 and Ø3.70 implants

GUIDE ANCHORING

Pink ring

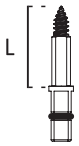


Ring	Internal Diameter (Ø)	Length (L)	Reference
○	3.75	3.50	3DAF1

Anodised ■

Grade 5 ELI Titanium

Crestal Anchor Pin



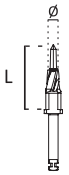
Ring	Length (L)	Reference
○	16.00	3DPIF1

● Double hex

Stainless Steel

START OF SURGERY

Soft tissue punch



Ring	Diameter (Ø)	Length (L)	Reference
○	2.90/3.70	16.00	3DMPTB1

45 USES · Stainless Steel

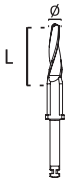
DRILLS

Pilot Drill 1

Ring	Diameter (Ø)	Length (L)	Reference
○	1.80/2.50	8.50	3DRPG185
	1.80/2.50	10.00	3DRPG110
	1.80/2.50	11.50	3DRPG115
	1.80/2.50	13.00	3DRPG113
	1.80/2.50	14.50	3DRPG114

45 USES · Stainless Steel

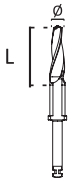
Final Drill Ø3.40 Implant



Ring	Diameter (Ø)	Length (L)	Reference
○	2.85/3.50	8.50	3DTDG3485
	2.85/3.50	10.00	3DTDG3410
	2.85/3.50	11.50	3DTDG3415
	2.85/3.50	13.00	3DTDG3413
	2.85/3.50	14.50	3DTDG3414

45 USES · Stainless Steel

Final Drill Ø3.40 Implant

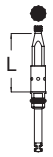


Ring	Diameter (Ø)	Length (L)	Reference
○	3.00/3.70	8.50	3DTDG3785
	3.00/3.70	10.00	3DTDG3710
	3.00/3.70	11.50	3DTDG3715
	3.00/3.70	13.00	3DTDG3713
	3.00/3.70	14.50	3DTDG3714

45 USES · Stainless Steel

KEYS

VPress insertion key. CA



Ring	Length (L)	Reference
○	14.50	3DSMRGV1
	20.50	3DLMRGV1

VPress subcrestal insertion key +1.50 CA

Ring	Length (L)	Reference
○	17.50	3DXMRGV1

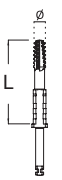
● Double hex

Stainless Steel

Instrument with DLC surface treatment.

TAPS

Surgical tap. CA (Tap)



Ring	Diameter (Ø)	Length (L)	Reference
○	3.40	21.50	3DMTAPG34
	3.70	21.50	3DMTAPG37

Stainless Steel

This product should be used in surgeries with types D1 and D2 "DENSE - High Density" bone densities.

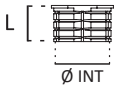
Refer to the detailed information on drilling sequences and implant insertion in this catalogue.

Surgical instruments

Instrumental for Ø4.00, Ø4.30 and Ø4.80 implants

GUIDE ANCHORING

Yellow ring

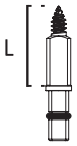


Ring	Internal Diameter (Ø)	Length (L)	Reference
○	4.85	3.50	3DAF2

Anodised

Grade 5 ELI Titanium

Crestal Anchor Pin



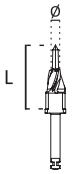
Ring	Length (L)	Reference
○	16.00	3DPIF2

● Double hex

Stainless Steel

START OF SURGERY

Soft tissue punch

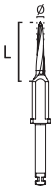


Ring	Diameter (Ø)	Length (L)	Reference
○	2.90/4.80	16.00	3DMPTB2

45 USES · Stainless Steel

DRILLS

Pilot Drill



Ring	Diameter (Ø)	Length (L)	Reference
○	2.50/3.50	6.00	3DRPG206
	2.50/3.50	8.50	3DRPG285
	2.50/3.50	10.00	3DRPG210
	2.50/3.50	11.50	3DRPG215
	2.50/3.50	13.00	3DRPG213
	2.50/3.50	14.50	3DRPG214

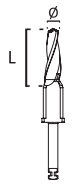
45 USES · Stainless Steel

Final Drill Ø4.00 Implant

Ring	Diameter (Ø)	Length (L)	Reference
○	3.20/4.00	6.00	3DTDG3906
	3.20/4.00	8.50	3DTDG3985
	3.20/4.00	10.00	3DTDG3910
	3.20/4.00	11.50	3DTDG3915
	3.20/4.00	13.00	3DTDG3913
	3.20/4.00	14.50	3DTDG3914

45 USES · Stainless Steel

Final Drill Ø4.30 Implant



Ring	Diameter (Ø)	Length (L)	Reference
○	3.40/4.30	6.00	3DTDG4006
	3.40/4.30	8.50	3DTDG4085
	3.40/4.30	10.00	3DTDG4010
	3.40/4.30	11.50	3DTDG4015
	3.40/4.30	13.00	3DTDG4013
	3.40/4.30	14.50	3DTDG4014

45 USES · Stainless Steel

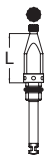
Final Drill Ø4.80 Implant

Ring	Diameter (Ø)	Length (L)	Reference
○	3.80/4.80	6.00	3DTDG4406
	3.80/4.80	8.50	3DTDG4485
	3.80/4.80	10.00	3DTDG4410
	3.80/4.80	11.50	3DTDG4415
	3.80/4.80	13.00	3DTDG4413

45 USES · Stainless Steel

KEYS

VPress insertion key. CA



Ring	Length (L)	Reference
○	14.50	3DSMRGV2
	20.50	3DLMRGV2

VPress subcrestal insertion key +1.50 CA

Ring	Length (L)	Reference
○	17.50	3DXMRGV2

● Double hex

Stainless Steel

Instrument with DLC surface treatment.

TAPS

Surgical tap. CA (Tap)

Ring	Diameter (Ø)	Length (L)	Reference
○	4.00	21.50	3DMTAPG40
	4.30	21.50	3DMTAPG43
	4.80	21.50	3DMTAPG48

Stainless Steel

This product should be used in surgeries with types D1 and D2 "DENSE - High Density" bone densities.

Refer to the detailed information on drilling sequences and implant insertion within this catalogue.

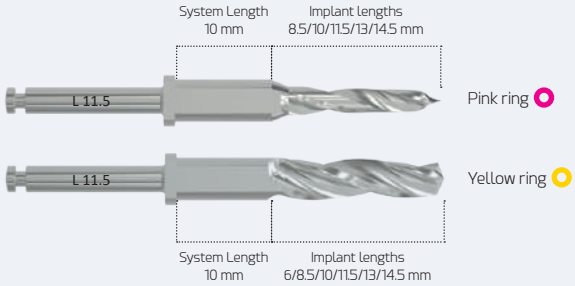
Surgical protocols

Surgical protocol

Features of the Galaxy 3D drilling system

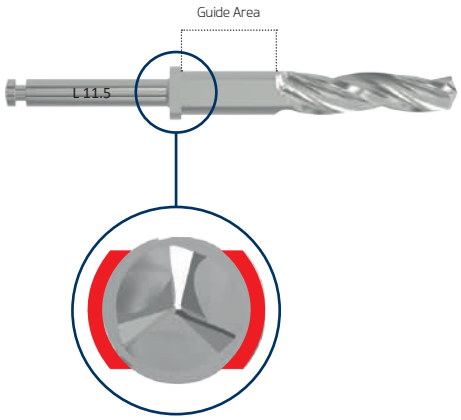
Ziacom® drill system (pilot drill)

Ziacom® implant system drills are made from stainless steel. Furthermore, they have a matte finish and therefore anti-reflective properties. The laser marking on the drill shank identifies its diameter and length.



Ziacom® Final Drills

These drills are designed for the creation of the surgical site. The drills are divided into 2 groups according to the type of ring used in the surgical guide. Additionally, 2 recommended protocols for use according to bone density are presented in the surgical kit box.



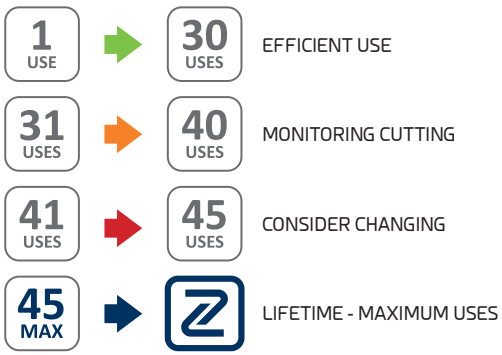
FINAL DRILL STOP

A stop, consisting of two blades (see red areas marked on image) has been incorporated into the design of the final drills, between guide area and the shank, to limit the penetration of the drill through the rings embedded in the surgical guides.

ZIACOM® DRILLS EFFICIENCY GUARANTEE

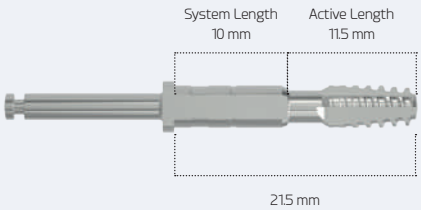
Ziacom® Galaxy 3D surgical drills (**pilot drills and final drills**) have a **maximum lifespan of 45 uses.** It is advisable to monitor the cutting condition at all times, mainly when nearing 31-40 uses, as after 41 uses it is necessary to consider changing the drills before reaching 45 uses.

Bear in mind that, depending on the size of the implant, bone density and your surgical protocol, not all of the various drills will be used equally - it is recommended that you monitor the number of uses for each instrument.



Ziacom® taps

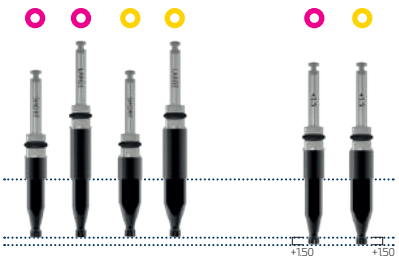
Taps are available for contra-angle handpieces. The laser marking on the drill shank identifies its diameter and length. Each tap is specific to each diameter, and may be used for all implant lengths of the same diameter - i.e. one single tap per implant diameter.



VPress insertion keys - DLC surface

The VPress insertion key for contra-angle handpieces has been specially designed for transporting Galaxy implants from their No-Mount vial to the surgical site ready for insertion. In the Galaxy 3D box, there are six different insertion keys, all laser marked on the shank to indicate their use according to the size of each ring and their length (Short and Large). Two of the keys are designed with an additional length of 1.5 mm (+1.50 mm) to position the Galaxy implants in their subcrestal position.

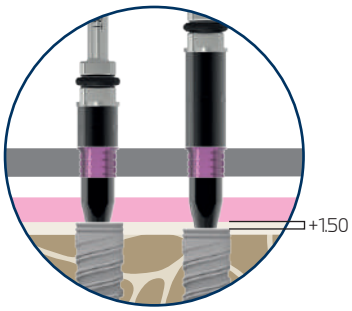
Short and long insertion keys for contra-angle handpieces



Juxtacrestal

Subcrestal
+1.50 mm

Depth within the implant platform marked on the insertion keys

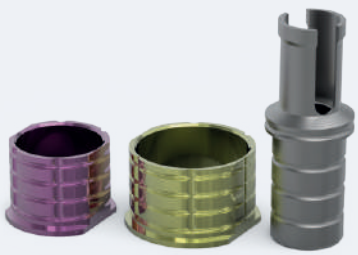


Rings

They are an important element in surgery with Galaxy 3D. They ensure the direction and length of the drilling as well as guide the insertion of the implant through the surgical bed.

There are 3 types of rings:

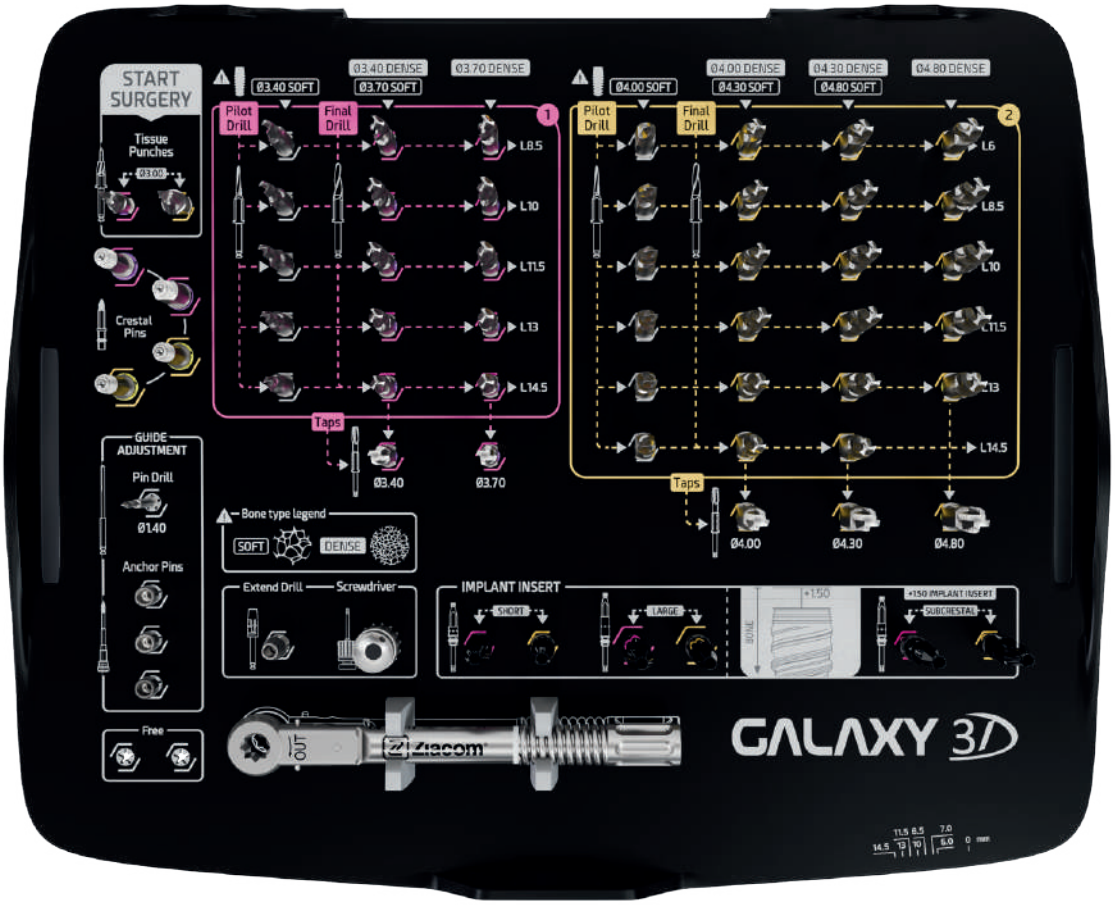
- Pink Ring: Ø3.40 and Ø3.70 implants
- Yellow Ring: for Ø4.00, Ø4.30 and Ø4.80 implants
- Grey Ring: drilling and positioning of the lateral anchor pins.



Surgical protocol

Features of the Galaxy 3D drilling system

Internal view of the Galaxy 3D surgical box



Recommendations on the maximum implant insertion torque

50 Ncm

The recommended insertion torque ranges between **35** and **50 Ncm** on a case-by-case basis.

To avoid deforming the driver and/or implant connection, insertions performed with a contra-angle handpiece (CA) must respect the recommended maximum rpm (25 rpm) and maximum torque (50 Ncm).

If the implant cannot be fully inserted using the recommended maximum torque, withdraw the implant, repeat the drilling and then re-insert it.

Check the final insertion torque with the adjustable dynamometric ratchet Ref. TORK50 or a contra-angle handpiece.

Exceeding the maximum torque (50 Ncm) when inserting the implant may result in:

- Irreversible deformations in the implant's internal connection.
- Irreversible deformations in the implant insertion instruments.
- Difficulty or impossibility in dismounting the instrument/implant assembly.

Galaxy implant

It is important to note that the drilling protocol for Galaxy implants varies significantly based on the implant diameter and the type of bone at the surgical site, and therefore it is important to pay special attention to these two aspects.

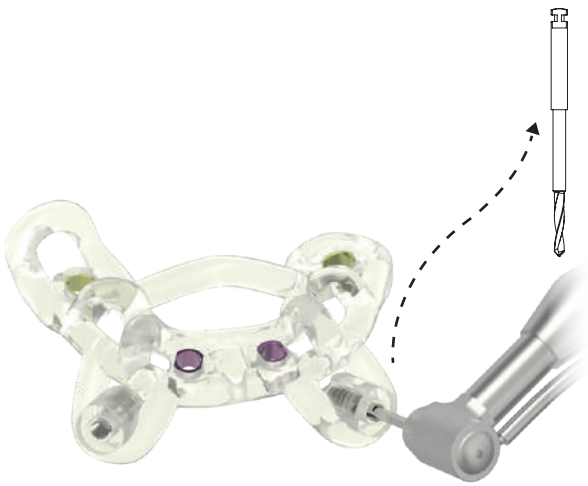
GALAXY

- **EXAMPLE:**
  Galaxy implant
  Ø3.70x13mm
  RP (Ø3.70 mm)
  Platform Ø 2.85mm
  Pink ring

Drilling protocol in SOFT bone (D3 - D4): example with Ø3.70x13 implant

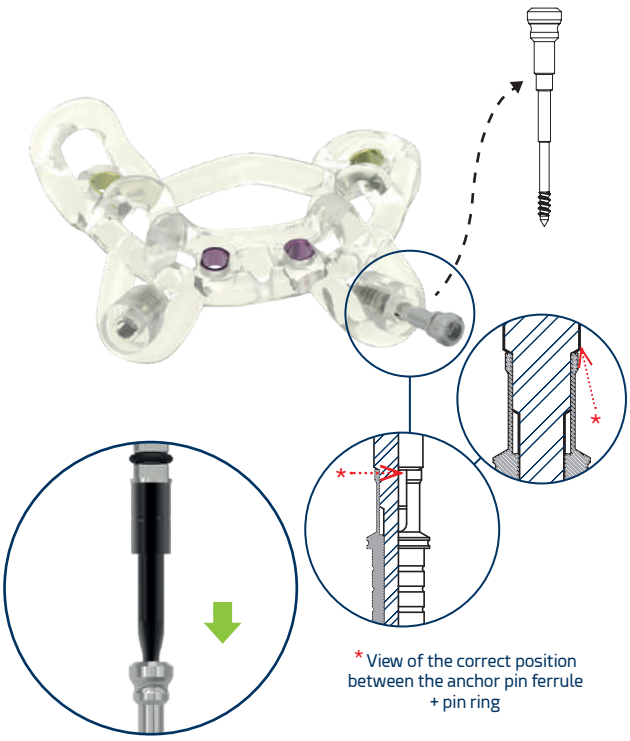
STEP 1 | Guide anchoring. Anchor pin drill

The Anchor Pin Drill **Ref. 3DPIF1** should be used to drill the bone, through the guide cylinder until it stops.



STEP 2 | Guide anchoring. Fixing pin

Insert the anchor pins **Ref. 3DPIFG** through the guide cylinders. An initial manual insertion can be carried out by turning clockwise and then using the VPress insertion key to complete the insertion, until it stops inside the guide cylinder. The stability of the guide must be checked throughout its extension.



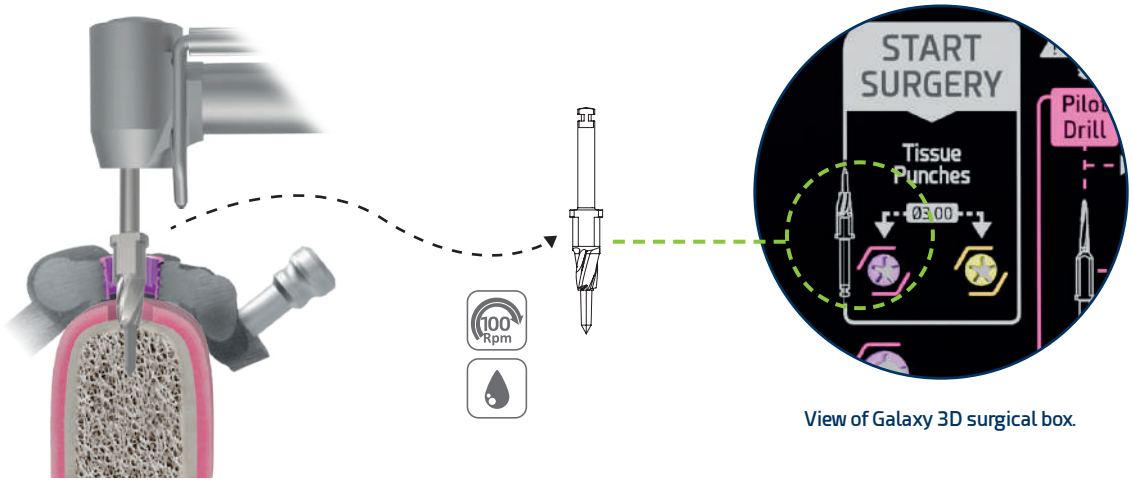
* View of the correct position between the anchor pin ferrule + pin ring

View of anchor pin connection + VPress insertion key

Surgical protocol

STEP 3 | Soft Tissue Punch

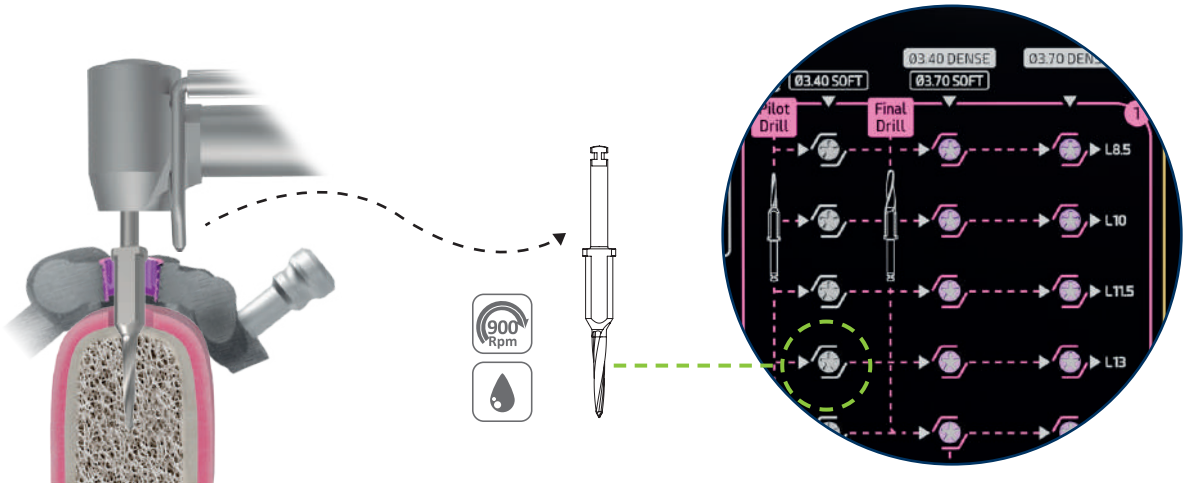
Remove the soft tissue with the Tissue Punch **Ref. 3DMPTB1**. This drill also performs an initial pilot drilling on the bone and evens out the bone ridge. Make sure to drill completely, so the drill stop must come into contact with the ring.



View of Galaxy 3D surgical box.

STEP 4 | Pilot drill

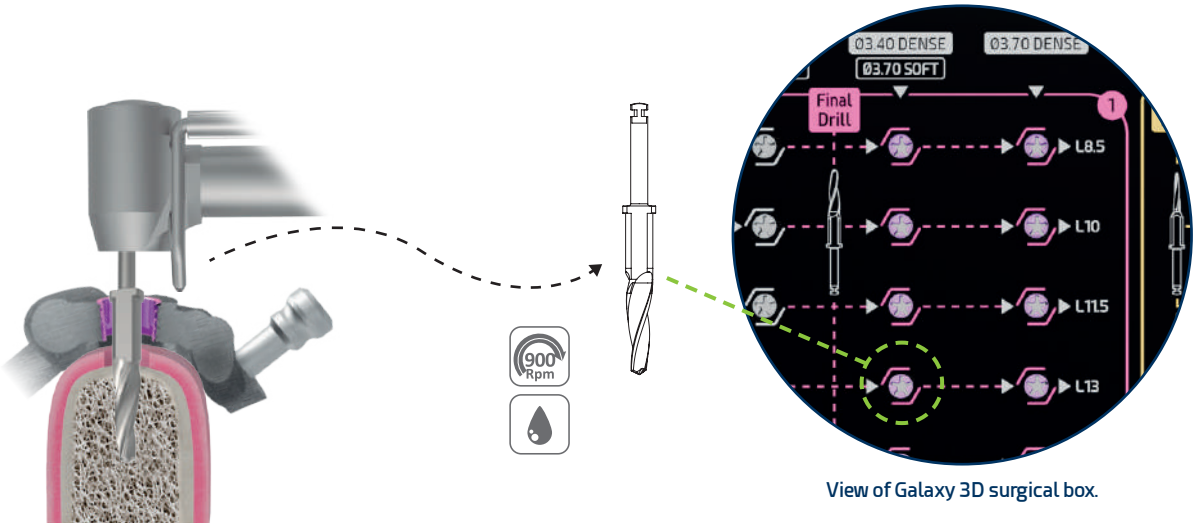
Begin the drilling sequence with the pilot drill **Ref. 3DRPG113**. We will use the pilot drill corresponding to the length of the implant.



View of Galaxy 3D surgical box.

STEP 5 | Drilling sequence

Drill the implant bed with the final drill **Ref. 3DTDG3413** corresponding to each implant length.



View of Galaxy 3D surgical box.

Important notes: Type SOFT D3 - Bone Density D4

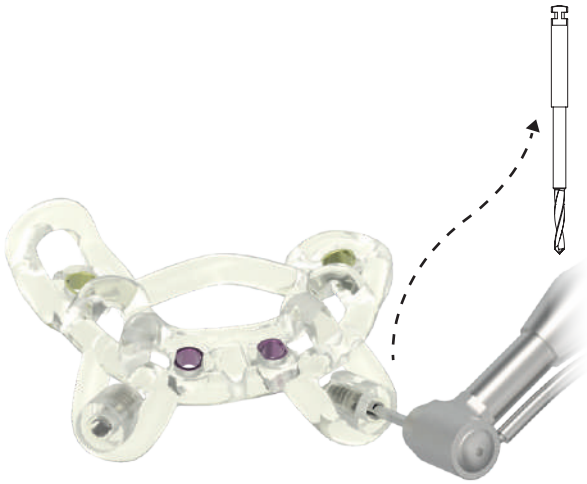
In the case of low bone density, the surgical drilling protocol indicated for SOFT bone density should be followed, leaving out the use of the last final drill and the surgical tap for each of the implant diameters. This protocol is printed on the box itself. Nevertheless, it is up to the discretion of the professional to decide to use the last final drill fully or partially, based on their clinical experience and the identification of the density of the existing bone at the site. This is particularly relevant in cases where the bone density varies significantly along the length of the osteotomy for the implant.

Surgical protocol

Drilling protocol in DENSE bone (D1 - D2): example with Ø3.70x13 implant

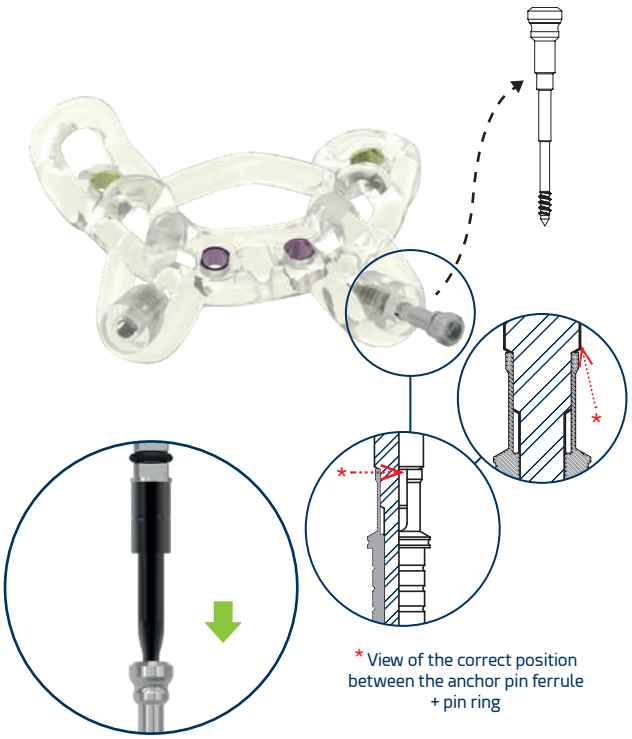
STEP 1 | Guide anchoring. Anchor pin drill

The Anchor Pin Drill **Ref. 3DPIF1** should be used to drill the bone, through the guide cylinder until it stops.



STEP 2 | Guide anchoring. Fixing pin

Insert the anchor pins **Ref. 3DPIFG** through the guide cylinders. An initial manual insertion can be carried out by turning clockwise and then using the VPress insertion key to complete the insertion, until it stops inside the guide cylinder. The stability of the guide must be checked throughout its extension.

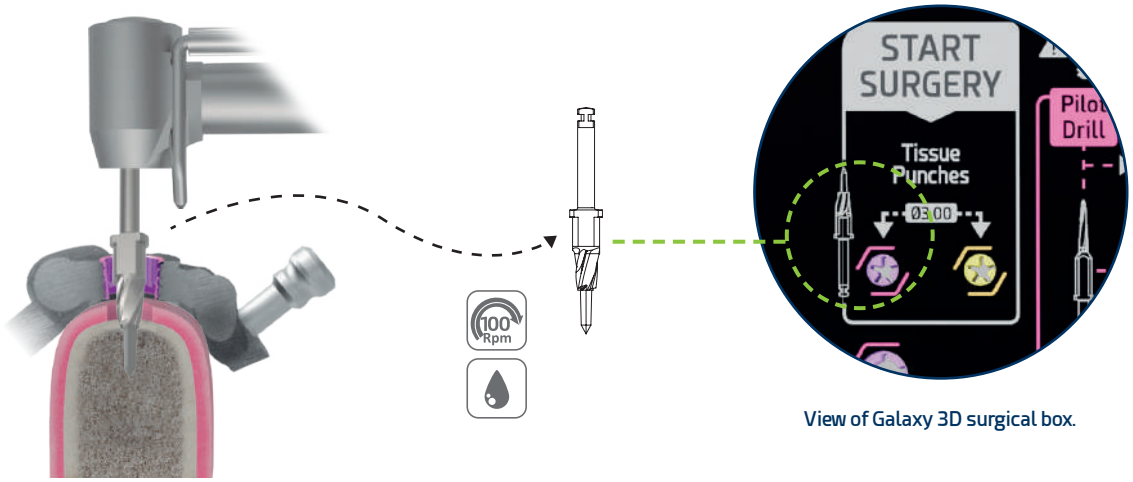


* View of the correct position between the anchor pin ferrule + pin ring

View of anchor pin connection + VPress insertion key

STEP 3 | Soft tissue punch

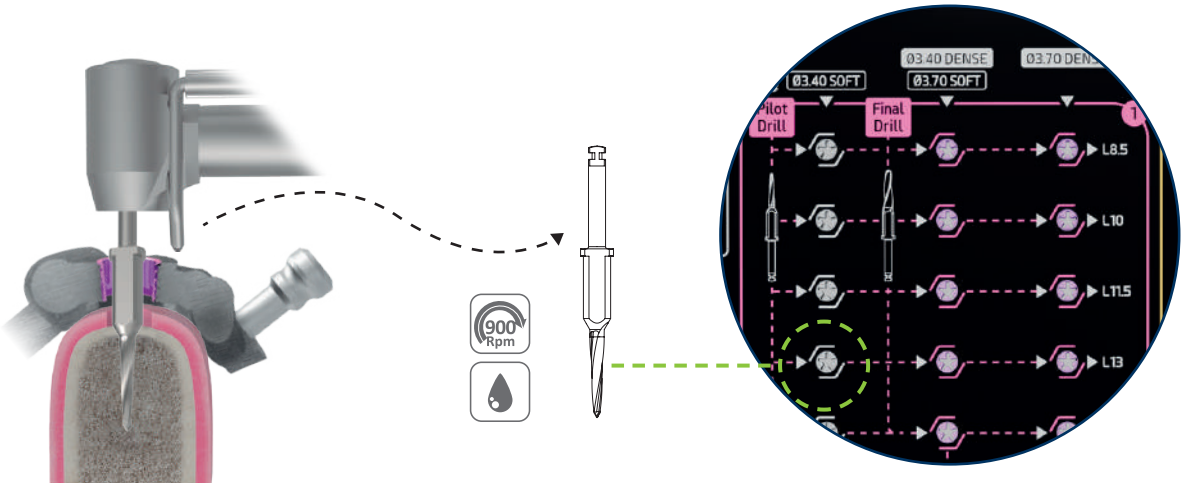
Remove the soft tissue with the Tissue Punch **Ref. 3DMPTB1**. This drill also performs an initial pilot drilling on the bone and evens out the bone ridge. Make sure to drill completely, so the drill stop must come into contact with the ring.



View of Galaxy 3D surgical box.

STEP 4 | Pilot drill

Begin the drilling sequence with the pilot drill **Ref. 3DRPG113**. We will use the pilot drill corresponding to the length of the implant.

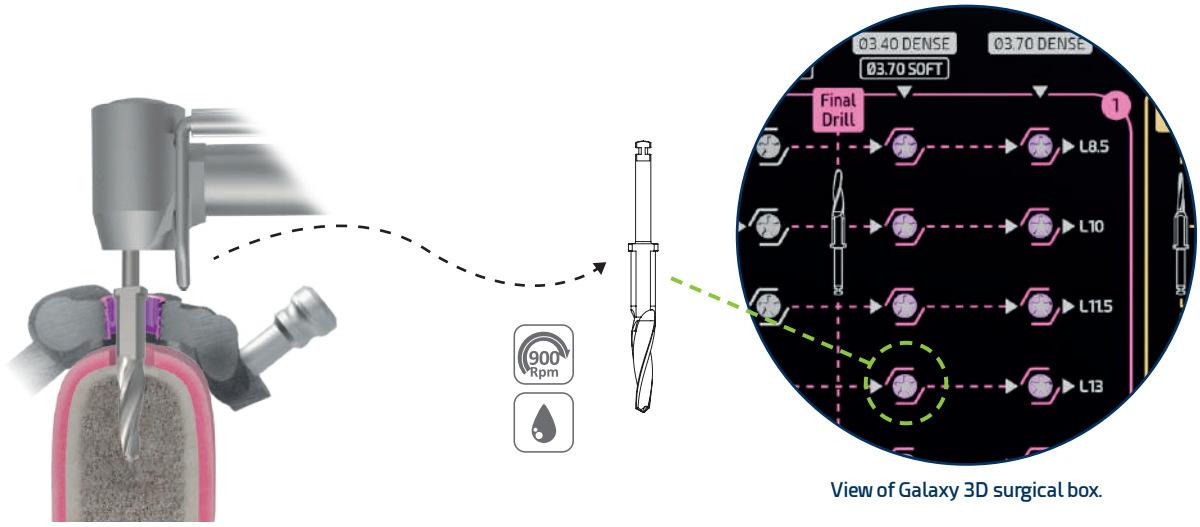


View of Galaxy 3D surgical box.

Surgical protocol

STEP 5 | Drilling sequence

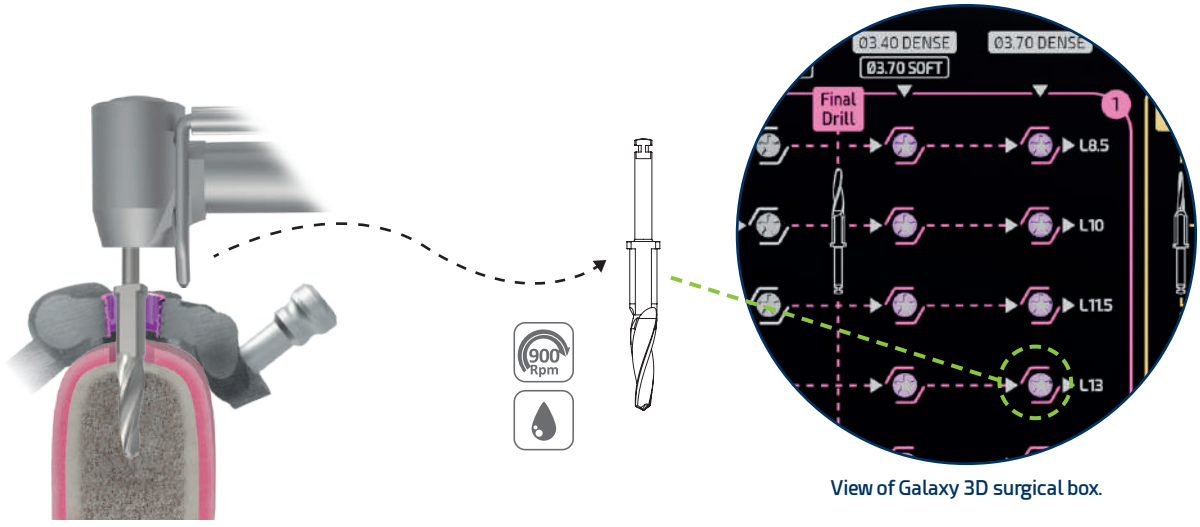
Drill the implant bed with the final drill **Ref. 3DTDG3413** corresponding to each implant length.



View of Galaxy 3D surgical box.

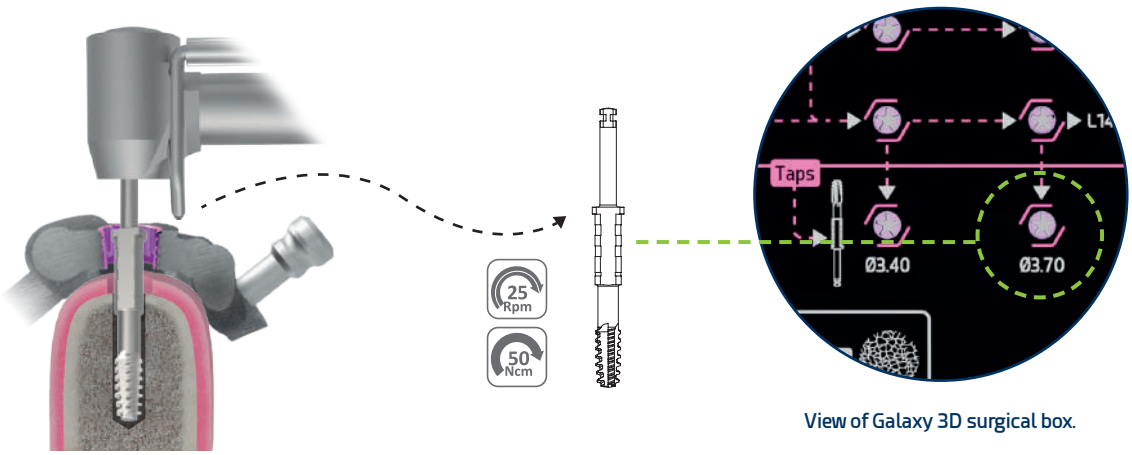
STEP 6 | Drilling sequence

Drill the implant bed with the final drill **Ref. 3DTDG3413** corresponding to each implant length.



View of Galaxy 3D surgical box.

The surgical tap (Tap) **Ref. 3DMTAPG37** or screw tap is used in "High-density" DENSE bone, as it facilitates implant insertion and avoids excessive compression on the bone.



View of Galaxy 3D surgical box.

Important notes: DENSE Bone Density Type D1-D2

In the case of high-density bone, the surgical drilling protocol indicated for DENSE bone density should be followed, the use of the surgical tap being necessary and mandatory. This protocol is printed on the box itself. Nevertheless, it is up to the discretion of the professional to decide whether to use the final surgical tap fully or partially, based on their clinical experience and the identification of the density of the existing bone at the site. This is particularly relevant in cases where the bone density varies significantly along the length of the osteotomy for the implant.

Surgical protocol

Galaxy implant

It is important to note that the drilling protocol for Galaxy implants varies significantly based on the implant diameter and the type of bone at the surgical site, and therefore it is important to pay special attention to these two aspects.

GALAXY

- **EXAMPLE:**

Galaxy implant

Ø4.80x13mm

RP (Ø4.80 mm)

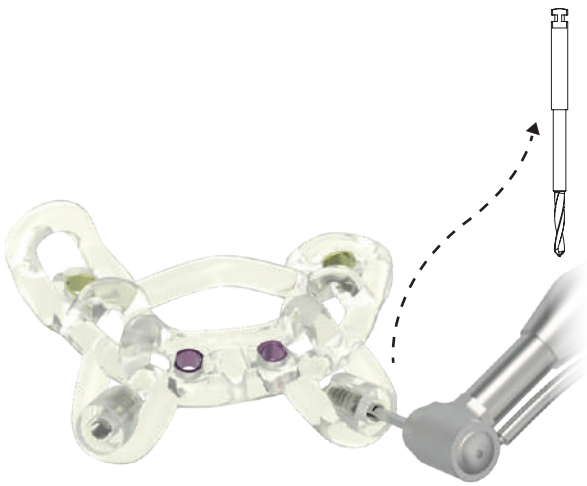
Platform Ø 2.85mm

Yellow ring

Drilling protocol in SOFT bone (D3 - D4): example with Ø4.80x13 implant

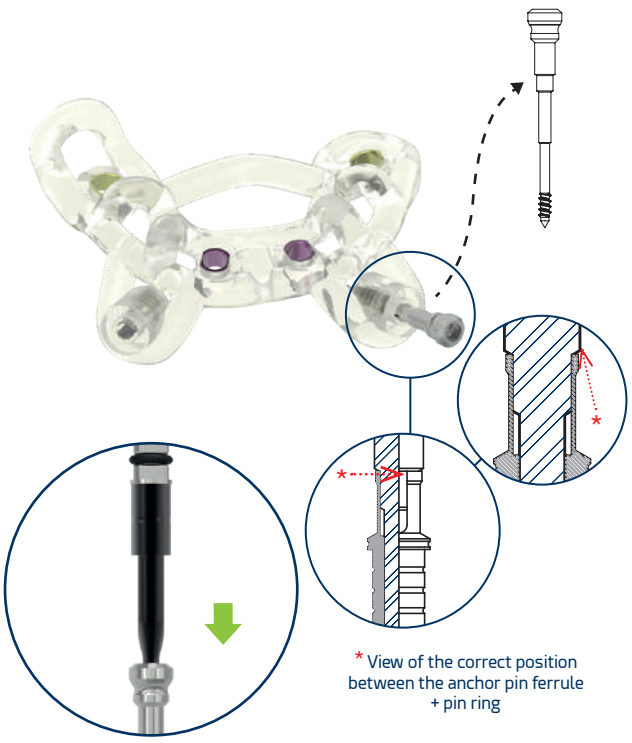
STEP 1 | Guide anchoring. Anchor pin drill

The Anchor Pin Drill **Ref. 3DPIF1** should be used to drill the bone, through the guide cylinder until it stops.



STEP 2 | Guide anchoring. Fixing pin

Insert the anchor pins **Ref. 3DPIFG** through the guide cylinders. An initial manual insertion can be carried out by turning clockwise and then using the VPress insertion key to complete the insertion, until it stops inside the guide cylinder. The stability of the guide must be checked throughout its extension.

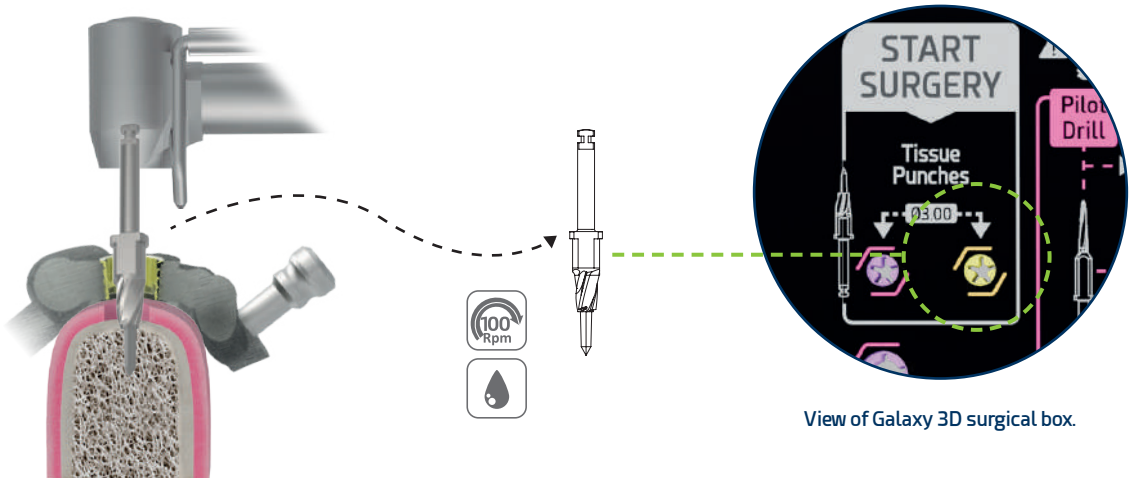


* View of the correct position between the anchor pin ferrule + pin ring

View of anchor pin connection + VPress insertion key

STEP 3 | Soft tissue punch

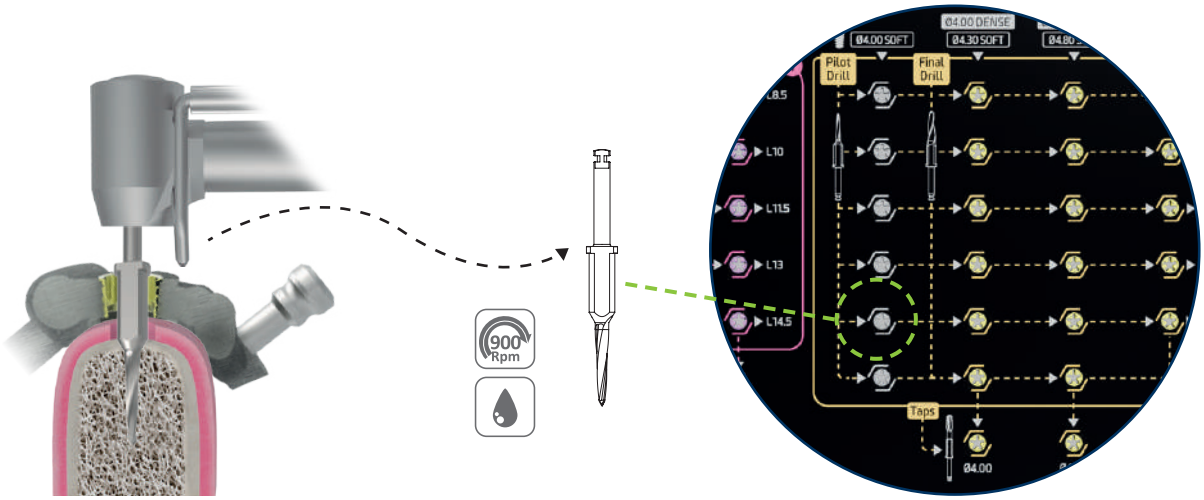
Remove the soft tissue with the Tissue Punch **Ref. 3DMPTB2**. This drill also performs an initial pilot drilling on the bone and evens out the bone ridge. Make sure to drill completely, so the drill stop must come into contact with the ring.



View of Galaxy 3D surgical box.

STEP 4 | Pilot drill

Begin the drilling sequence with the pilot drill **Ref. 3DRPG213**. We will use the pilot drill corresponding to the length of the implant.

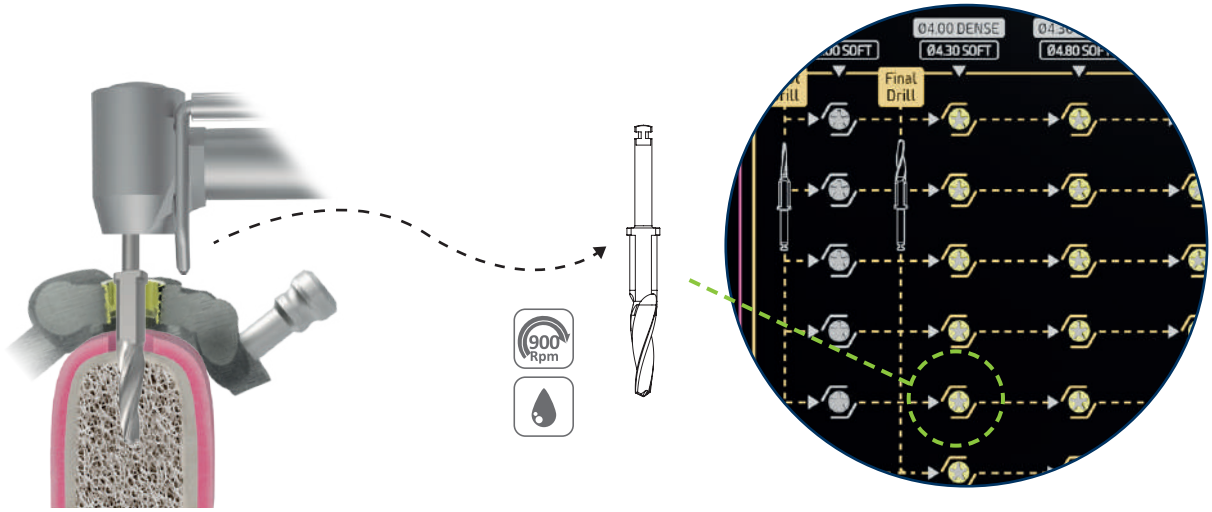


View of Galaxy 3D surgical box.

Surgical protocol

STEP 5 | Drilling sequence

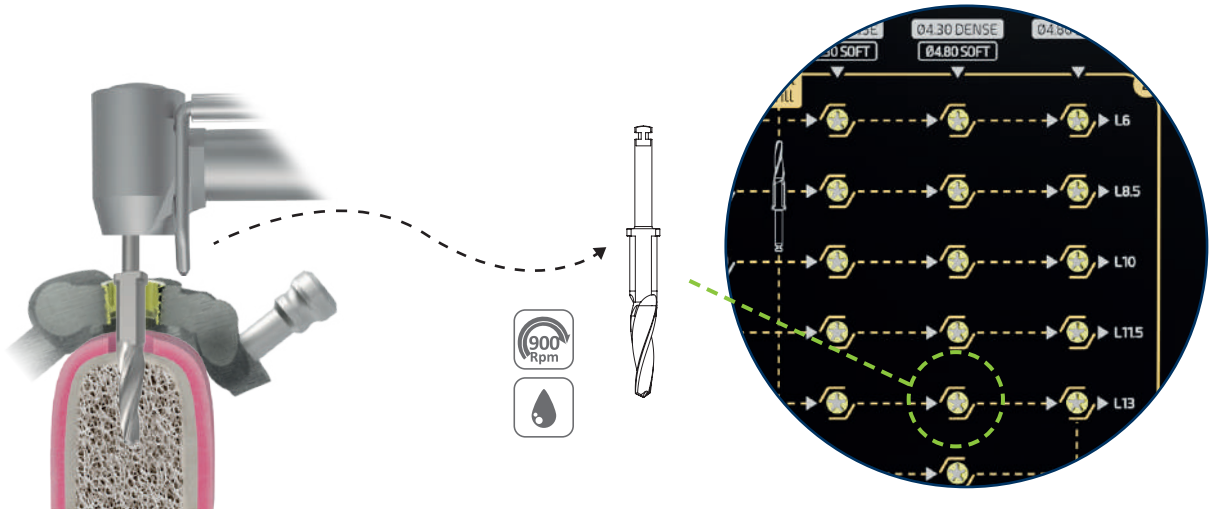
Drill the implant bed with the final drill **Ref. 3DTDG3913** corresponding to each implant length.



View of Galaxy 3D surgical box.

STEP 6 | Drilling sequence

Drill the implant bed with the final drill **Ref. 3DTDG4013** corresponding to each implant length.



View of Galaxy 3D surgical box.

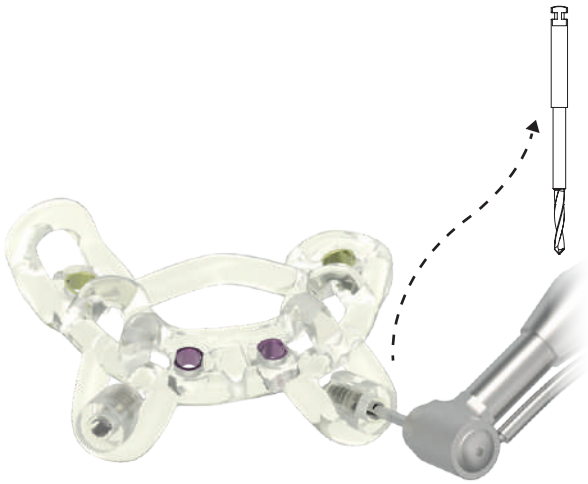
Important notes: Type SOFT D3 - Bone Density D4

In the case of low bone density, the surgical drilling protocol indicated for SOFT bone density should be followed, leaving out the use of the last final drill and the surgical tap for each of the implant diameters. This protocol is printed on the box itself. Nevertheless, it is up to the discretion of the professional to decide to use the last final drill fully or partially, based on their clinical experience and the identification of the density of the existing bone at the site. This is particularly relevant in cases where the bone density varies significantly along the length of the osteotomy for the implant.

Drilling protocol in DENSE bone (D1-D2): example with Ø4.80x13 implant

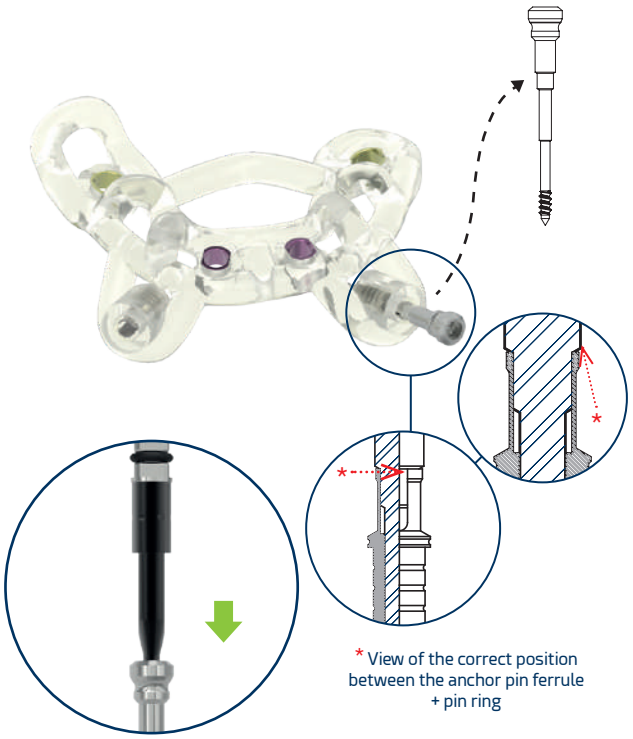
STEP 1 | Guide anchoring. Anchor pin drill

The Anchor Pin Drill **Ref. 3DPIF1** should be used to drill the bone, through the guide cylinder until it stops.



STEP 2 | Guide anchoring. Fixing pin

Insert the anchor pins **Ref. 3DPIFG** through the guide cylinders. An initial manual insertion can be carried out by turning clockwise and then using the VPress insertion key to complete the insertion, until it stops inside the guide cylinder. The stability of the guide must be checked throughout its extension.



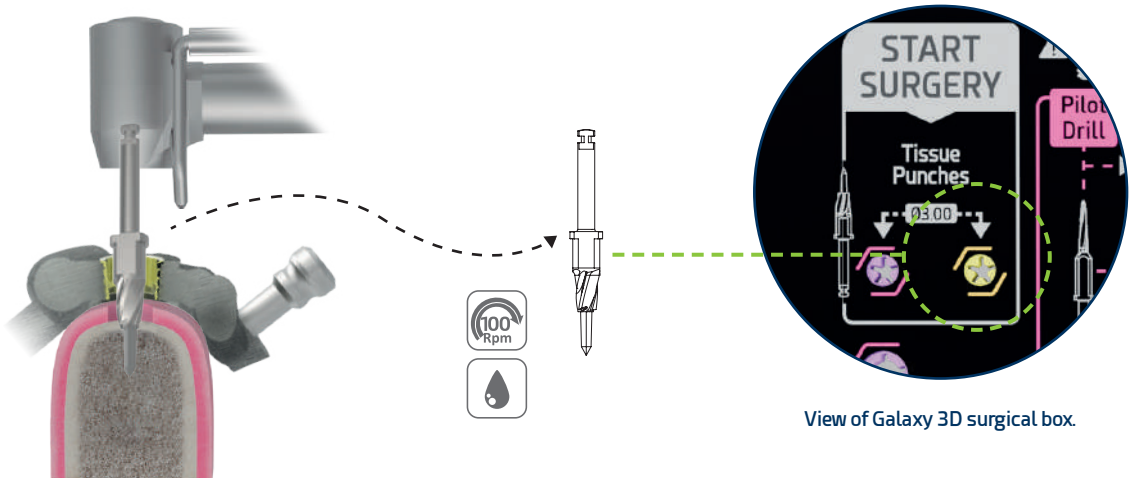
View of anchor pin connection + VPress insertion key

* View of the correct position between the anchor pin ferrule + pin ring

Surgical protocol

STEP 3 | Soft tissue punch

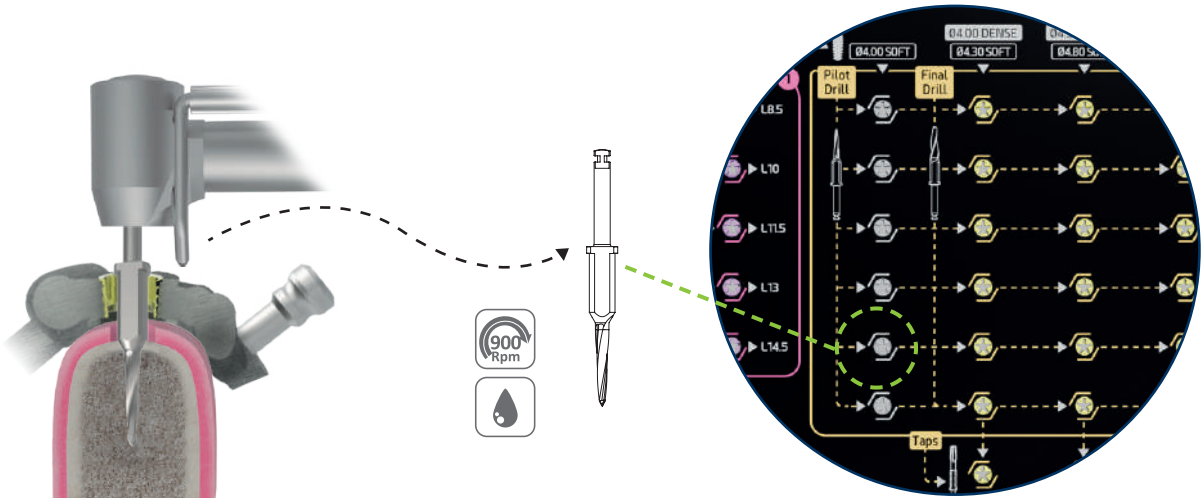
Remove the soft tissue with the Tissue Punch **Ref. 3DMPTB2**. This drill also performs an initial pilot drilling on the bone and evens out the bone ridge. Make sure to drill completely, so the drill stop must come into contact with the ring.



View of Galaxy 3D surgical box.

STEP 4 | Pilot drill

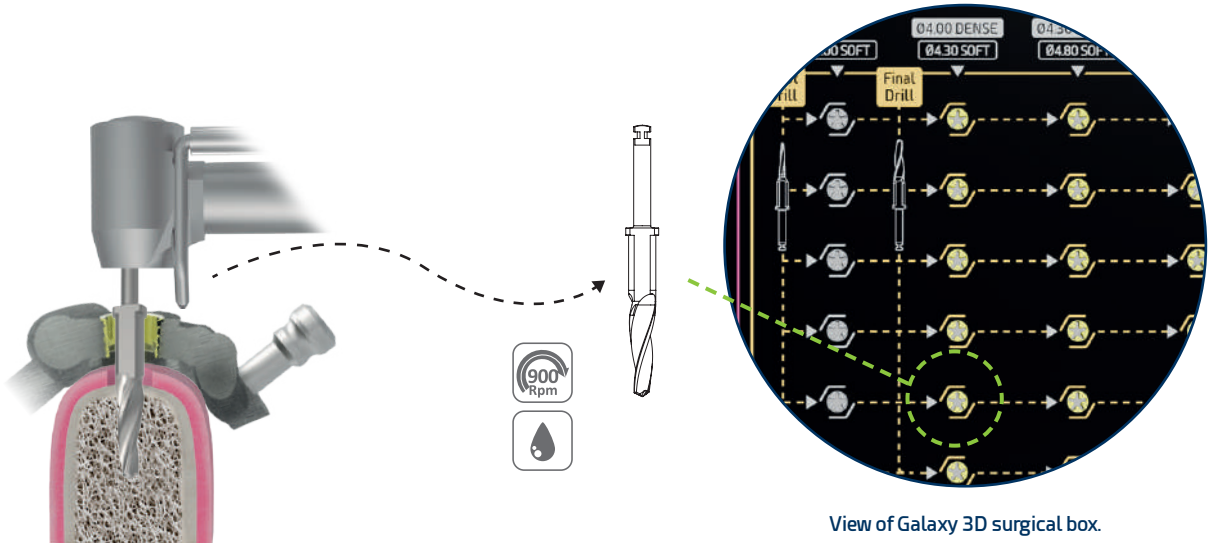
Begin the drilling sequence with the pilot drill **Ref. 3DRPG213**. We will use the pilot drill corresponding to the length of the implant.



View of Galaxy 3D surgical box.

STEP 5 | Drilling sequence

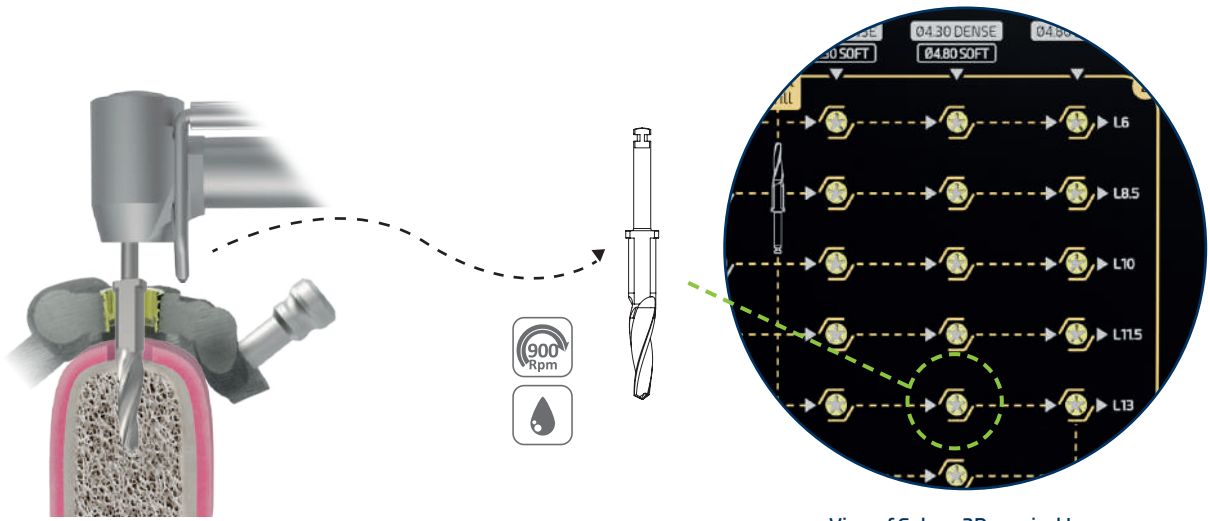
Drill the implant bed with the final drill **Ref. 3DTDG3913** corresponding to each implant length.



View of Galaxy 3D surgical box.

STEP 6 | Drilling sequence

Drill the implant bed with the final drill **Ref. 3DTDG4013** corresponding to each implant length.

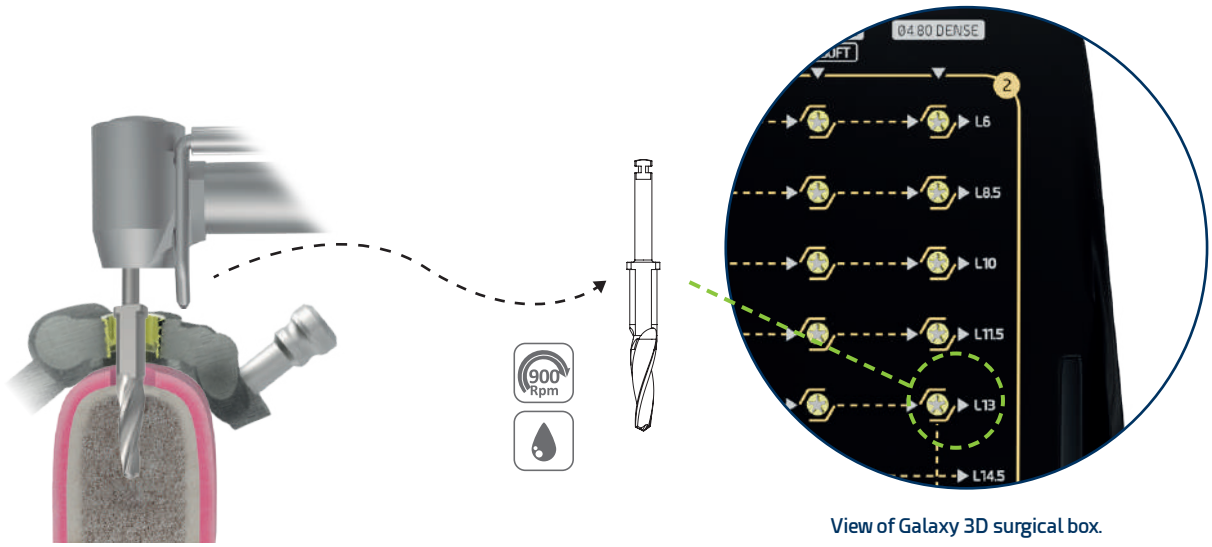


View of Galaxy 3D surgical box.

Surgical protocol

STEP 7 | Drilling sequence

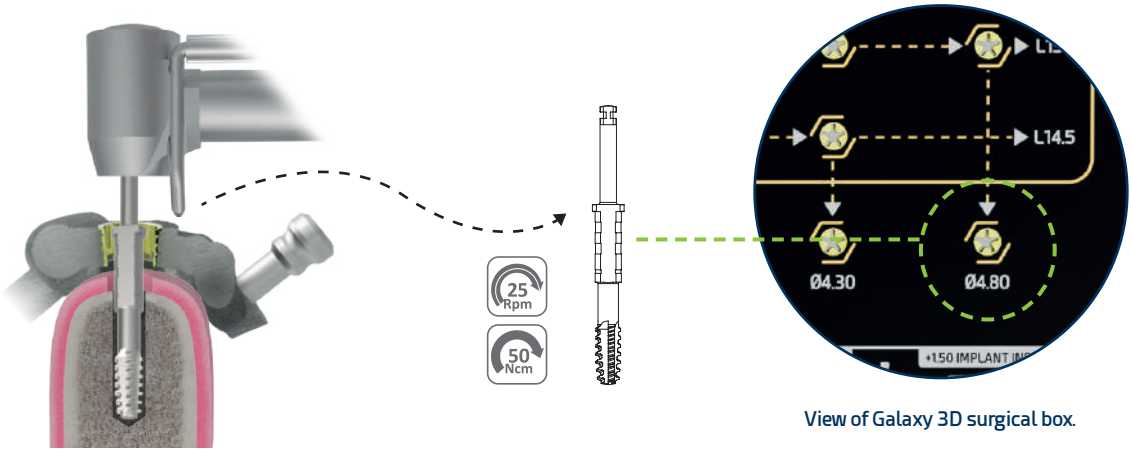
Drill the implant bed with the final drill **Ref. 3DTDG4413** corresponding to each implant length.



View of Galaxy 3D surgical box.

STEP 8 | Surgical tap

The surgical tap **Ref. 3DMTAPG48** or screw tap is used in "High-density" DENSE bone, as it facilitates implant insertion and avoids excessive compression on the bone.



View of Galaxy 3D surgical box.

Important notes: DENSE Bone Density Type D1-D2

In the case of high-density bone, the surgical drilling protocol indicated for DENSE bone density should be followed, the use of the surgical tap being necessary and mandatory. This protocol is printed on the box itself. Nevertheless, it is up to the discretion of the professional to decide whether to use the final surgical tap fully or partially, based on their clinical experience and the identification of the density of the existing bone at the site. This is particularly relevant in cases where the bone density varies significantly along the length of the osteotomy for the implant.

Surgical protocol

Implant insertion with Ziacom® No Mount | **Titansure**

Ziacom® No Mount

Surface treatment

Titansure

STEP 1 | Unpacking the implant

1.1 Press the word "PRESS" and tear open the box.

1.2 Remove the top of the carton and take out the blister pack.

1.3 Carefully remove the seal from the blister pack.

1.4 Turn the vial containing the implant onto a sterile cloth in the operating area.

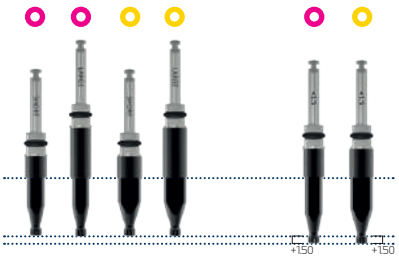
1.5 Hold the vial upright with one hand. Remove the cap by turning and lifting it.

1.6 Remember to remove the label from the implant and to adhere it to the patient's implant card and medical record to ensure that the product is traceable.

STEP 2 | Choosing the right insertion instrument

Use the VPress insertion key. CA of the preferred length and insert it into the contra-angle:

- **Pink Ring** - Ref. **3DSMRGV1/3DLMRGV1** (Juxtacrestal)
  - Ref. **3DXMRGV1** (Subcrestal +1.50 mm).
- **Yellow Ring** - Ref. **3DSMRGV2/ 3DLMRGV2** (Juxtacrestal)
  - Ref. **3DXMRGV2** (Subcrestal +1.50 mm).



Juxtacrestal

Subcrestal
+1.50 mm

STEP 3 | Removing the implant from its vial

Hold the vial containing the implant upright in one hand and insert the selected driver into the implant with the other hand. Remove the implant by lifting it vertically out of the vial.

Implant insertion with Ziacom® No Mount | **Titansure Active**

Ziacom® No Mount

Surface treatment

Titansure Active

STEP 1 | Unpacking the implant

1.1 Press the word "PRESS" and open the carton.

1.2 Remove the top of the carton and take out the blister pack.

1.3 Carefully remove the seal from the blister pack.

1.4 Turn the vial containing the implant onto a sterile cloth in the operating area.

1.5 Hold the vial upright with one hand. Remove the cap by turning and lifting it.

NOTE: Take care when opening the vial as the implant is submerged in a bioactive liquid.

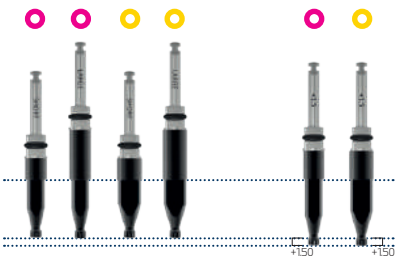
1.6 Remember to remove the label from the implant and to adhere it to the patient's implant card and medical record to ensure that the product is traceable.

NOTE: Do not reuse any leftover liquid.

STEP 2 | Choosing the right insertion instrument

Use the VPress insertion key. CA of the preferred length and insert it into the contra-angle:

- **Pink Ring** - Ref. **3DSMRGV1/3DLMRGV1** (Juxtacrestal)
  - Ref. **3DXMRGV1** (Subcrestal +1.50 mm).
- **Yellow Ring** - Ref. **3DSMRGV2/ 3DLMRGV2** (Juxtacrestal)
  - Ref. **3DXMRGV2** (Subcrestal +1.50 mm).



Juxtacrestal

Subcrestal +1.50 mm

STEP 3 | Removing the implant from its vial

Hold the vial containing the implant upright in one hand and insert the selected insertion key into the implant with the other hand. Remove the implant by lifting it vertically out of the vial.

NOTE:
Take care when opening the vial so as not to spill the bioactive liquid. Leftover bioactive liquid cannot be reused.

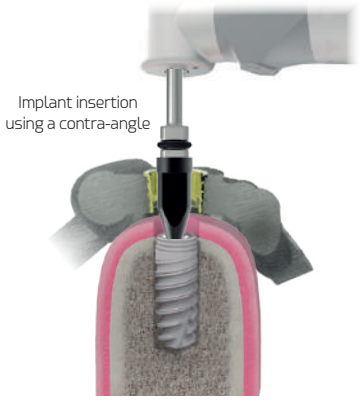
Surgical protocol

Galaxy implant insertion

STEP 1 | Inserting the implant

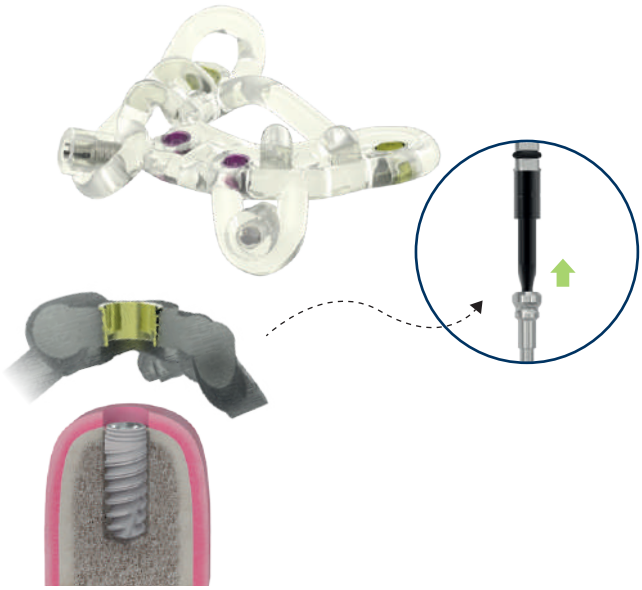
When inserting the implant with a contra-angle, use a maximum speed of 25 rpm. The recommended insertion torque ranges from 35 to 50 Ncm.

If resistance is met during insertion, turn the implant anti-clockwise and then continue to insert after waiting a few seconds. Repeat this process as many times as necessary.



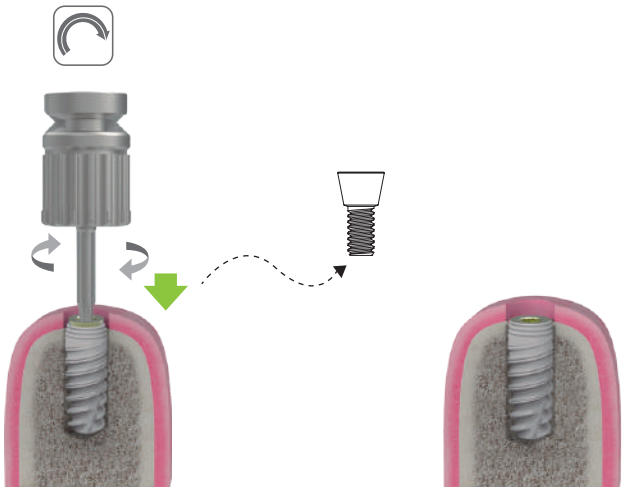
STEP 2 | Removal of the surgical guide

Remove the **surgical guide** by extracting the anchor pins with the VPress insertion key, turning anti-clockwise and then dismantling the guide from the mouth.



STEP 3 | Placing the cover screw (Optional)

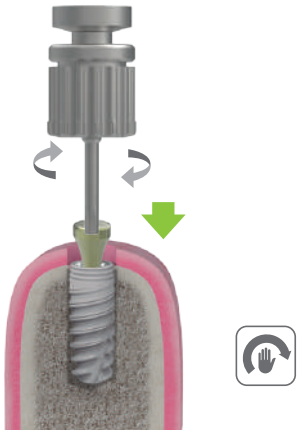
Bring the cover screw **Ref. GLYRT** towards the implant with the manual surgical screwdriver, **Ref. LMSD** preventing it from falling and accidentally being swallowed. Insert the screw into the implant until it locks, applying manual torque in a clockwise direction.



STEP 4 | Placing the healing abutment

Insert the selected healing abutment using a manual surgical screwdriver **Ref. LMSD**.

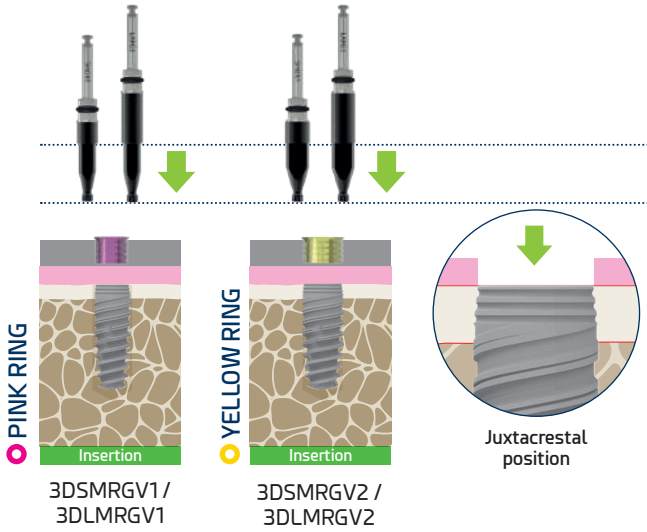
The choice of healing abutment will depend on each individual case. It should match the implant platform and also the height of the gingival tissue in order to prevent occlusion of the abutment. If the abutment is too tall, it may subject the implant to premature loading, compromising the osseointegration process.



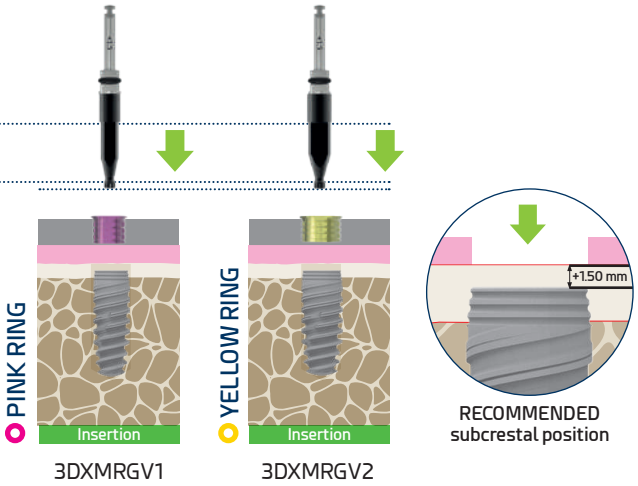
Crestal placement of the implant

The drilling protocols are described so that the platform for the Galaxy implants is juxtacrestal. Nevertheless, recommendations are to leave the platform slightly subcrestal.

Juxtacrestal insertion



Subcrestal insertion +1.50 mm



Subcrestal position

- Improves mucosal preservation.
- Improves the thickness of the keratinised tissue.
- Suggests improved bone preservation when combined with tapered connection.
- Helps obtain an ideal emergence profile in aesthetic areas.
- Prevents the implant surface from being exposed, which can facilitate bacterial growth preservation of the crestal bone.
- Prevents fibrous connective tissue formation at the implant interface.
- Better preservation of the crestal bone.
- Allows abutments with a greater height to be used. Recommended to preserve slim-biotype bone tissue (≤1.0 mm) at the gingiva.
- Reduces the risk of suffering peri-implant pathologies.

Surgical protocol

Bone types

Misch classification (1988)

TYPE **D1** BONE

- Dense cortical and dense trabecular bone.
- > 1250 HU

TYPE **D2** BONE

- Porous cortical and dense trabecular bone.
- 850 - 1250 HU

TYPE **D3** BONE

- Porous cortical and fine trabecular bone.
- 350 - 850 HU

TYPE **D4** BONE

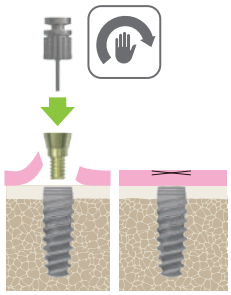
- Thin crestal cortical and fine trabecular bone.
- 150 - 350 HU

HU = Hounsfield Units

IMPORTANT
In order to simplify the surgical drilling protocols, we have created quick drilling guides, in which the criteria for bone types are amalgamated, with D1-D2 treated as "DENSE - High-Density" bone, and D3-D4 bone types as "SOFT - Low-Density" bone .

Handling of cover screw

Place the cover screw in the screwdriver. Move the cover screw towards the implant while taking care not to drop it and cause its accidental ingestion. Insert it into the implant applying manual torque in a clockwise direction.



Considerations for temporisation and immediate loading

Immediate temporisation and immediate loading are procedures that involve the placement of the prosthesis within 72 hours after implant surgery. The fundamental difference between these procedures is whether or not the prosthesis will have a functional load.

Adequate primary stability of the implant at the time of insertion is crucial to consider placing a provisional or immediately loaded prosthesis. This stability can be objectively measured by the insertion torque, which must be equal to or greater than 40-45 Ncm or by analysing the resonance frequency (ISQ value), which should be greater than or equal to 70.

IMMEDIATE TEMPORISATION

Immediate temporisation involves thorough monitoring of occlusion, both in central (closed) position, and during lateral or dynamic movements that occur during mastication. By freeing the provisional from any contact in these situations, the transfer of forces to the implant is prevented.

The main objectives of immediate temporisation are:

- Immediate closure of edentulous spaces in aesthetic areas.
- Guided regeneration of the gingival emergence profile due to the presence of the provisional crown or bridge.

IMMEDIATE LOADING

The principle of immediate loading involves the controlled transfer of contact from the moment of placement of the restoration while the restoration is in occlusion; therefore we distinguish between:

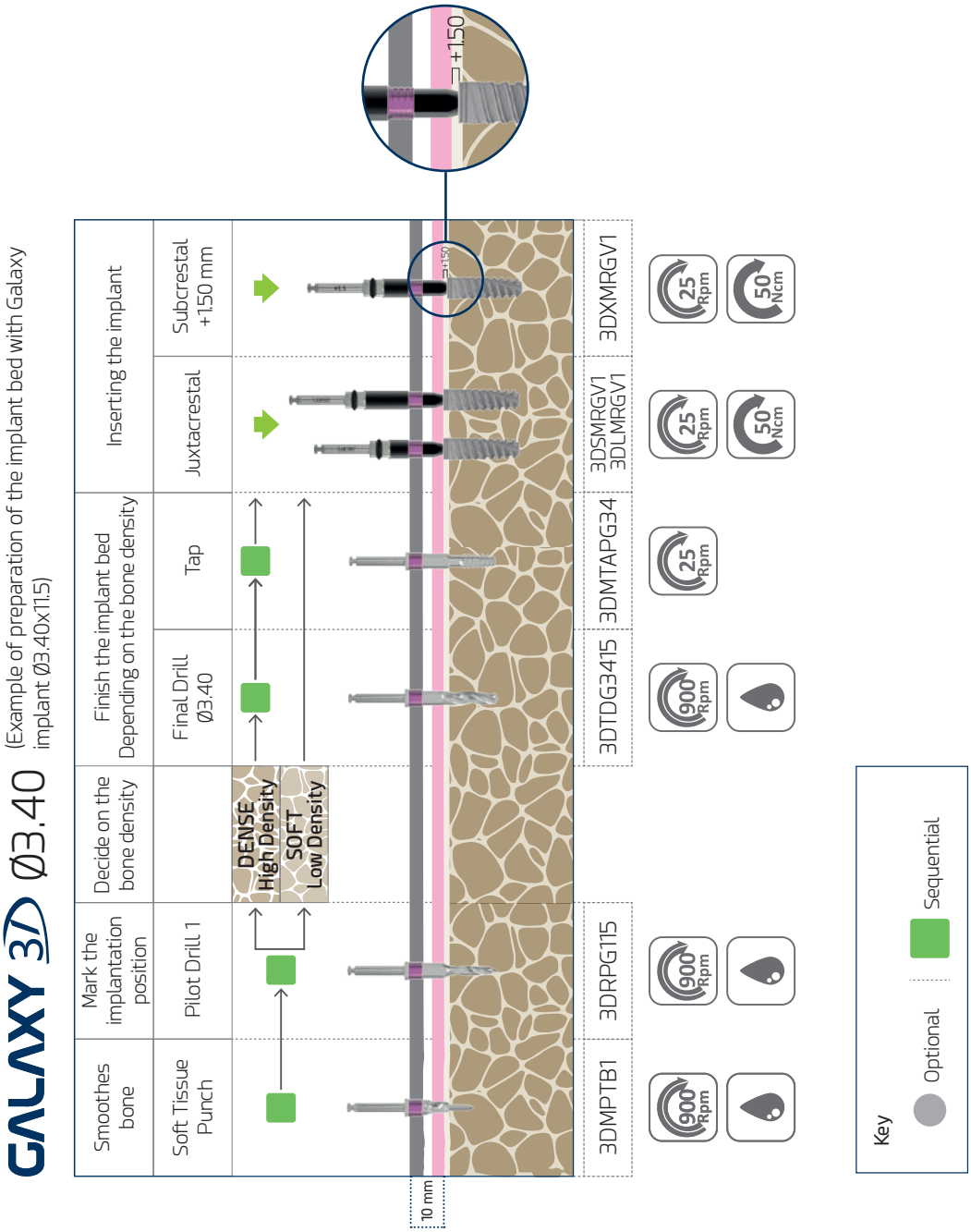
- Progressive immediate loading, using an acrylic provisional restoration as the initial restoration (released in dynamic occlusion).
- Definitive immediate loading, with rigid material and active occlusion from day one.

Both processes involve risks to the success of the osseointegration of the implant, so it is up to the practitioner, based on clinical experience and the case in question, whether or not to place an immediate provisional restoration and/or immediate loading.

Drilling protocol for Ø3.40 implants

Rotation | Irrigation required | Ø Drill diameter | Torque

Detailed speeds are recommended

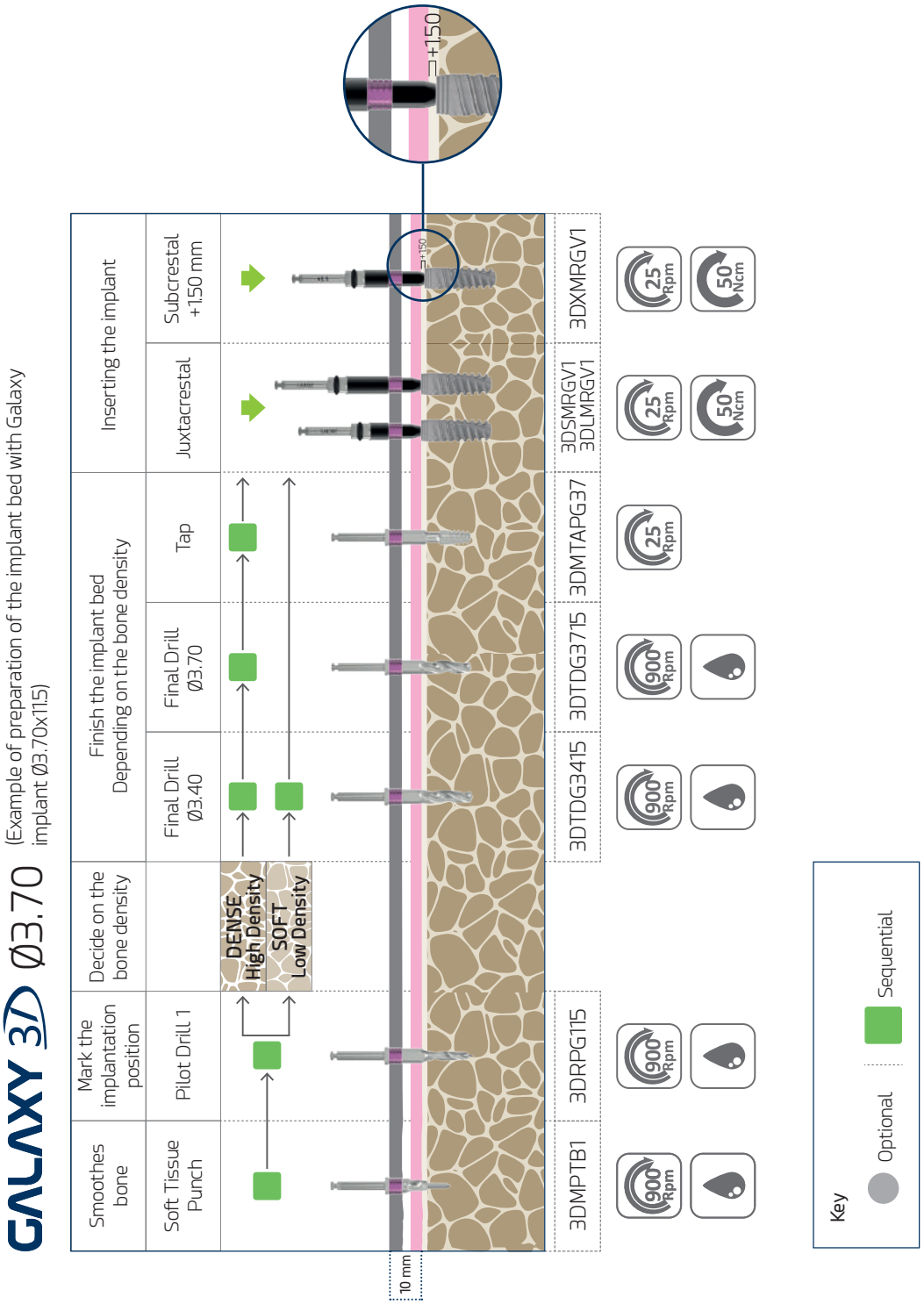


Simplified surgical protocol

Drilling protocol for Ø3.70 implants

Rotation | Irrigation required | Ø Drill diameter | Torque

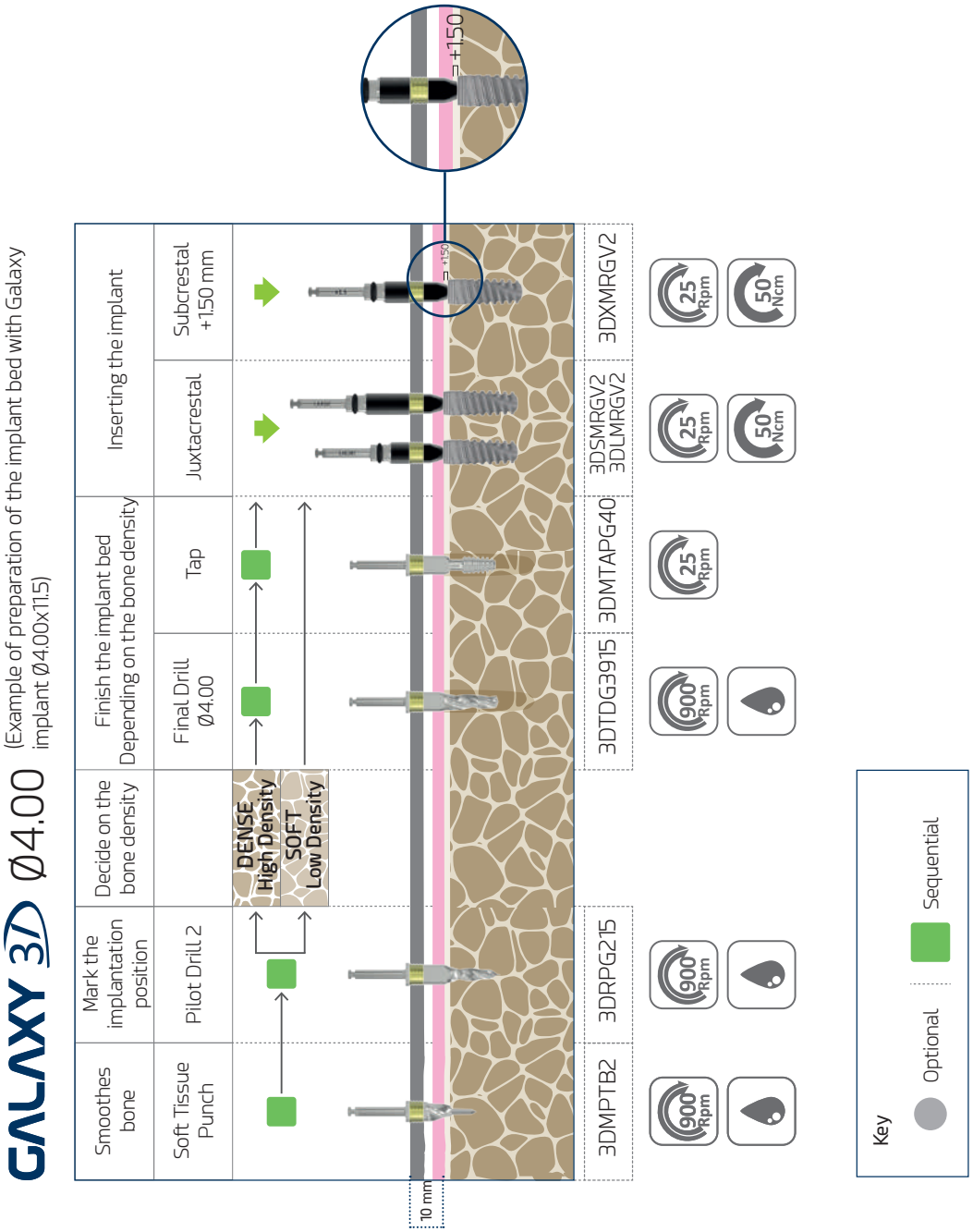
Detailed speeds are recommended



Drilling protocol for Ø4.00 implants

Rotation | Irrigation required | Ø Drill diameter | Torque

Detailed speeds are recommended

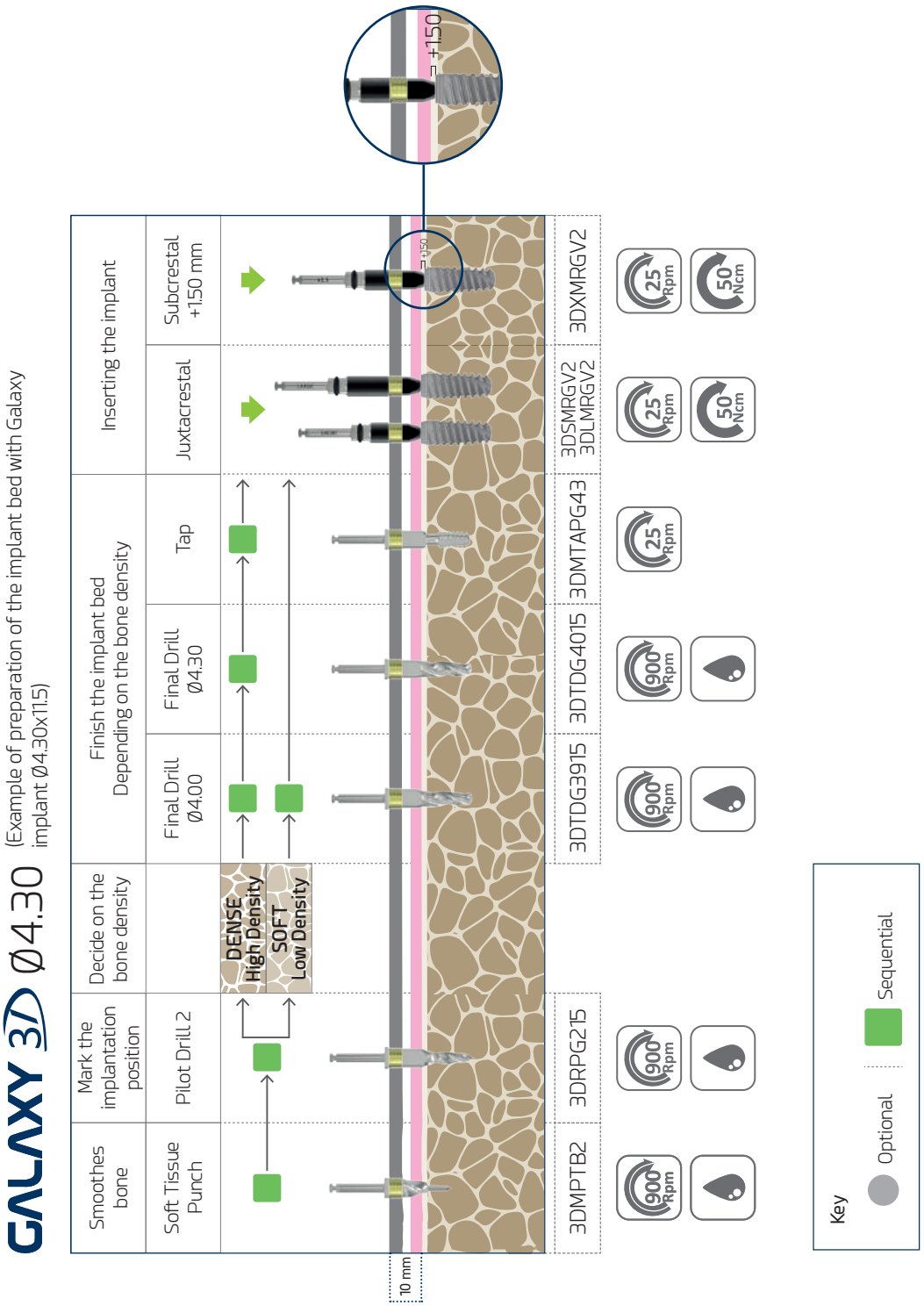


Simplified surgical protocol

Drilling protocol for Ø4.30 implants

Rotation | Irrigation required | Ø Drill diameter | Torque

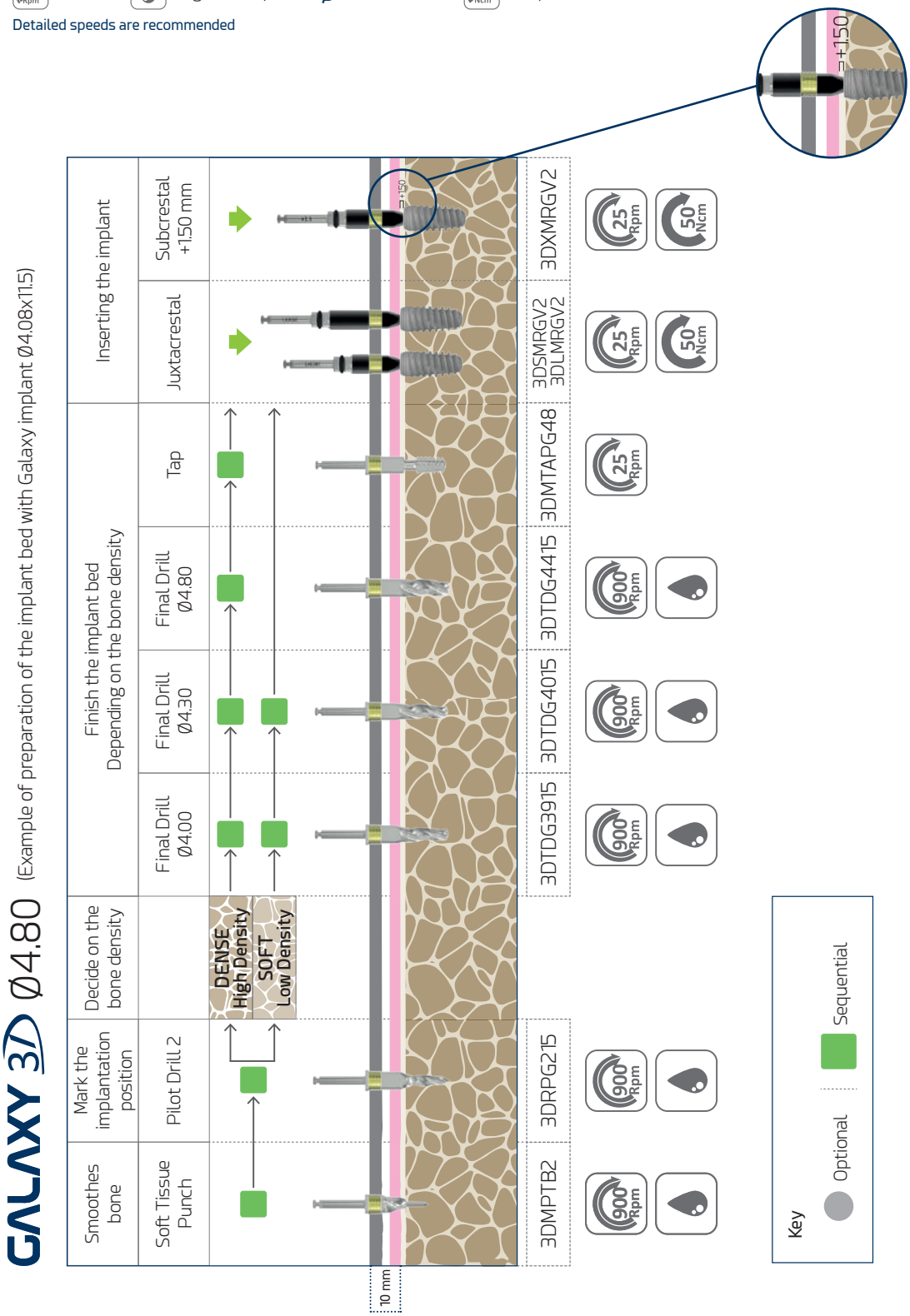
Detailed speeds are recommended



Drilling protocol for Ø4.80 implants

Rotation | Irrigation required | Ø Drill diameter | Torque

Detailed speeds are recommended




GALAXY 3D

Cleaning, disinfection and sterilisation

Cleaning, disinfection and sterilisation

The protocols described in this section must only be carried out by personnel qualified to clean, disinfect and sterilise the dental materials specified herein.

Cleaning and disinfection instructions

Applicable for surgical and prosthetic instruments and boxes.

Disassembly

1. Disassemble* the instruments that need to be cleaned and disinfected, such as manual ratchets, drills or drill stops.
2. Remove all the different components from the surgical or prosthetic kit box for correct cleaning.

Cleaning and disinfection

For disinfection of instruments and surgical kit boxes:

1. Submerge the instruments in a detergent/disinfectant solution** suitable for dental instruments to help eliminate any adhered biological residues. If an ultrasound bath is available***, confirm that the detergent/disinfectant solution is indicated for use with this type of equipment.
2. Manually remove any biological residues with a non-metallic brush and pH-neutral detergent.
3. Rinse with copious water.
4. When cleaning surgical and prosthetic kit boxes, always use a pH-neutral detergent and non-abrasive tools to avoid damaging the surface of the boxes.
5. Dry the materials with disposable, lint-free, cellulose cloths or compressed air.

For disinfection of plastic caps and the protective disk:

1. Submerge for 10 minutes in a neat benzalkonium chloride solution.
2. Rinse with distilled water.
3. Dry the caps and disk prior to use.

Inspection

1. Check that the instruments are perfectly clean; if not, repeat the cleaning and disinfection steps.
2. Discard any instruments with imperfections and replace them before the next surgery.
3. Check that the instruments and surgical and prosthetic kit boxes are perfectly dry before reassembling the parts and proceeding with sterilisation.

* See the assembly and disassembly manuals at **www.ziacom.com/biblioteca**

** Follow the instructions from the disinfectant's manufacturer to determine the correct concentrations and times.

** Follow the instructions from the ultrasound bath's manufacturer to determine the correct temperature, concentration and times.

Sterilisation instructions for steam autoclaves

Applicable to orthodontic implants, abutments, kit, surgical and prosthetic boxes, pins, fixing screws and mesh membranes.

1. Place the material in individual sterilisation pouches and seal the pouches. For joint sterilisation, place the instruments in their surgical kit box, place the box in a sterilisation pouch and seal the pouch.
2. Place the pouches to be sterilised in the autoclave.
3. Sterilise in a steam autoclave at 134°C/273°F (max. 137°C/276°F) for 4 min (minimum) at 2 atm. Dynamometric torque wrenches must be sterilised in 3 vacuum cycles at 132°C/270°F for at least ≥ 4 minutes and vacuum dried for at least 20 minutes.

For the United States only: The validated and recommended sterilisation cycle for the US must be performed in a steam autoclave at 132ºC/270°F for at least 15 minutes with a drying time of at least 15-30 minutes.

IMPORTANT
Make sure the drying stage is allowed to run to completion, otherwise the products may be damp.
Check the sterilisation equipment if the materials or sterilisation pouches are damp at the end of the sterilisation cycle.
Perform the necessary maintenance actions on the autoclave according to the established periodicity and following the manufacturer's instructions.

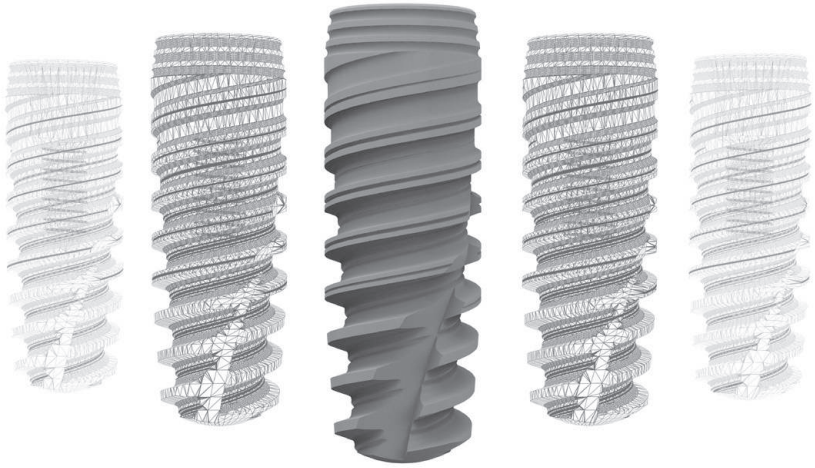
Storage of Ziacom® products

- Store the products in their original packaging in a clean, dry place until they are to be used.
- After sterilisation, keep the products in the sealed sterilisation pouches in a clean, dry location.
- Never exceed the use by date indicated by the manufacturer of the sterilisation pouches.
- Always follow the instructions of the manufacturer of the sterilisation pouches.

General recommendations

- Never use damaged or dirty material; never reuse single-use products. The user is responsible for following the instructions described in this document correctly.
- Pay attention to piercing or sharp elements. Gloves should be worn when cleaning the materials to avoid accidents during handling.
- Follow the safety instructions indicated by the manufacturer of the disinfectant.
- The product's sterility cannot be guaranteed if the sterilisation pouch is open, damaged or damp.
- Respect all stages of the sterilisation process. If the materials or sterilisation pouches contain traces of water or moisture, check the autoclave and repeat the sterilisation.
- Orthodontic abutments and implants are supplied UNSTERILISED and must always be sterilised before use.
- Instruments and surgical and prosthetic kit boxes are supplied UNSTERILISED and must always be sterilised before use and cleaned and disinfected after use.
- Sterilisation, cleaning and disinfection processes gradually deteriorate the instruments. Inspect the instruments thoroughly to detect any signs of deterioration.
- Avoid contact between products made from different materials (steel, titanium, etc.) during the cleaning, disinfection and sterilisation processes.
- Ziacom Medical SL recommends these instructions are implemented for the correct maintenance and safety of their products; accordingly, the company refuses any liability for any damage to the products that could arise if the user applies alternative cleaning, disinfection and sterilisation procedures.

See the latest version of the cleaning, disfection and sterilisation instructions at **www.ziacom.com/biblioteca**



See the updated general conditions of sale at **www.ziacom.com**.

Check the availability of each product in your country.

See the latest version of the catalogues at **www.ziacom.com**.

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