

IMPLANT SYSTEM

XCN[®]

**SURGICAL
PROCEDURE**



The pictures and illustrations in this brochure are for information purposes only and they are not intended to replace the methods or procedures for diagnosis and treatment planning of the Dental surgeon, Dentist and Dental Technician regarding the needs of each patient. Leone Spa disclaims any liability or any other obligation expressed or implied in this brochure.

DISCLAIMER

The Surgical Procedure and the use of the products of the XCN® Leone Implant System described in the following pages are intended for Professionals experienced in dental implant techniques.

In case of lack of basic notions, we suggest to attend specific courses in order to reach a high level of knowledge and practice in the use of implants. The rules on the use of the products described below represent a group of standard instructions that must be adjusted to the single needs and to the particular situations that may occur according to the manual ability, to the experience and to the diagnosis made by the legally qualified medical operator.

It is not ascribed to the manufacturer the duty of monitoring the procedures of use of the product. A correct and appropriate use of the instruments and products related to the XCN® Leone Implant System shall completely be reverted to the clinician. The surgical procedure hereunder described is merely indicative as any single treatment case is assigned to the experience of the operator.

As every medical operator well knows, a correct procedure and a perfect manufacture of the prosthesis may sometimes be followed by not satisfactory results owing to particular situations not imputable to responsibility of the dental operator or the manufacturer.

TREATMENT PLANNING

Indications

SINGLE-TOOTH EDENTULISM, DISTAL EDENTULISM, MULTIPLE EDENTULISM, TOTAL EDENTULISM.

Contraindications

For contraindications and side effects read the instructions for use enclosed in the package of each product and available in our web site www.leone.it in the section **Services/Quality**

PREOPERATORY EXAMS

Before starting the surgical intervention, the patients have to be subjected to a series of exams; single cases have to be evaluated in the opinion of the clinician.

Anamnesis

It is the first approach to the patient and it represents a fundamental tool to recognize both risk factors and contraindications. Moreover, anamnesis allows for the evaluation of patient's expectations and priorities and of patient's degree of compliance and motivation. Anamnesis can help in evaluating the need for extra exams in addition to the routine ones (when the presence of pathologies that were not reported by the patient is suspected) and when particular situations drive to deem a complete medico-surgical exam may be necessary.

Objective exam

It consists of:

- inspection of the periodontal tissues, of the oral mucosa and of the teeth along with an initial evaluation of the occlusal relationships (skeletal Class, characteristics of the opposing arch and related potential problems, type of occlusion, interarch distance), of the presence of parafunctions, of the degree of oral hygiene, of the aesthetic conditions, of the morphology of the edentulous crest and the space available for the replacement of the prosthesis.
- palpation of the soft tissues and implant sites for a preliminary evaluation of the bone morphology and thickness.
- a complete periodontal probing for the appraisal of the absence of both gingivitis and pockets
- Examination of the dental casts mounted in an articulator for a comparison with the information derived from previous exams, creation of a diagnostic set-up, and, if necessary, the implementation of a surgical template.

Radiographic exams

PANORAMIC RADIOGRAPH: frequently, this radiograph allows an appraisal of the bone height and the relationships between implant site and adjacent structures, such as maxillary sinuses, nasal cavities, and mandibular canal. It is also possible to identify concavities and ossification defects due to previous tooth extractions.

INTRAORAL RADIOGRAPH: it is very helpful for the determination of the mesio-distal distance between the roots, and the apico-coronal availability of bone.

LATERAL CEPHALOGRAM: it is useful when interventions on the mandibular symphysis are planned.

COMPUTERIZED TOMOGRAPHY CONE BEAM: it is advisable to remind that previous radiographic exams provide two-dimensional images which do not give information on bone thickness. In order to obtain this useful information a Cone Beam computerized tomography (CBCT) is necessary: it provides three-dimensional images, thus allowing for an accurate evaluation of bone morphology and, sometimes, bone density.

Instrumental or laboratory exams or medical advices

When necessary, in cases where a pathology is suspected on the basis of anamnesis or clinical records.

IMPLANT SELECTION

The number and dimensions (diameter and length) of the implants to be used are determined by the following factors:

1. amount of bone available
 2. characteristics of the implant site
 3. masticatory load
 4. aesthetic results
 5. type of the prosthetic restoration
 6. type of the surgical procedure followed
- Further and particular single situations must be evaluated by the clinician.

For the evaluation of implant treatment with the Leone system, XCN implants are included in the libraries of the most popular dental software for implant treatment planning and 3D radiographic diagnostics.

In addition, templates are available in which XCN Leone implants are represented in various scales: actual dimensions, increased by 10% and increased by 25% to match distortions created by the X-ray unit.

Small diameter implants (implant-abutment connection 2.2) are not recommended for the posterior region.

Small diameter implants, 8 mm long, are intended for use as a support in prosthesis composed of two or more implants of any diameter and length.

*In case of single implants, **do not** fabricate restorations with mesial or distal cantilever extensions.*

*Do not place the **Max Stability implants** in thick cortical bone, equivalent to D1 bone density according to Misch Classification.^[1]*

*The **2.9 Narrow implant** is suitable for cases with very narrow spaces. It is mainly indicated for narrow bony ridges and for limited interdental spaces in the anterior region, specifically for the upper lateral incisors and lower central and lateral incisors.*

*The use of the **6.5 Short implant** shall be restricted to cases with limited vertical bone availability.*

It is not intended to be associated with sinus lift procedures, immediate loading or one-stage surgical technique.

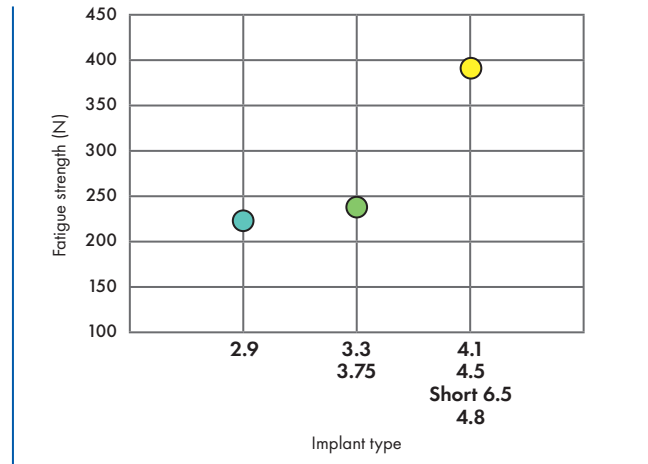
XCN® IMPLANTS ARE INTENDED FOR PLACEMENT AT THE LEVEL OF ALVEOLAR CREST OR BELOW THE LEVEL OF ALVEOLAR CREST UP TO 2 mm SUBCRESTALLY. DO NOT PLACE LEONE IMPLANTS ABOVE THE LEVEL OF ALVEOLAR CREST.

^[1]Misch CE, Density of bone: effect on treatment plans, surgical approach, healing and progressive bone loading, Int J Oral Implant 1990; 6:23-31

XCN® implant system is characterized by high mechanical strength, validated through fatigue testing performed according to ISO 14801 standard.^[2]

The results are:

- Narrow implants Ø 2.9 mm: **220 N**;
- Classix implants Ø 3.3 mm and Max Stability implants Ø 3.75 mm: **240 N**;
- Classix implants Ø 4.1 mm, Max Stability implants Ø 4.5 mm, Short 6.5 implants, Classix implants Ø 4.8 mm: **392 N**.^[3, 4]



In the literature, in comparison, it is reported that the average force generated during mastication is 145 N with inclinations within 10°,^[5, 6] It should also be stressed that very high masticatory forces^[7, 8] can be generated due to many individual and prosthetic factors, such as crown height, cantilever and restoration type, which locally can exceed the strength limit of the implants, especially in case of single or unsplinted implants.

^[2]ISO 14801:2007 (E), Dentistry - Implants - Dynamic fatigue test for endosseous dental implants, International Organization for Standardization, Geneva, 2007

^[3]Barlattani A, Sannino G, Mechanical evaluation of an implant-abutment self-locking taper connection: finite element analysis and experimental tests, Int J Oral Maxillofac Implants 2013;28:e17-e26

^[4]Gervasi G, Impianto Leone Exacone 2,9 mm: caratteristiche e comportamento biomeccanico, Exacone News 25, 2017:18-22

^[5]Carlsson GE, Haraldson T, Functional response, In: Branemark P-I, Zarb GA, Albrektsson T, Eds. Tissue integrated prostheses. Osseointegration in clinical dentistry. Chicago: Quintessence, 1985:155-63

^[6]Graf H, Occlusal forces during function, In: Proceedings of Symposium on Occlusion: Research on Form and Function. University of Michigan School of Dentistry, Ann Arbor: Rowe NH (Ed.), 1975:90-111

^[7]Craig RG, Restorative dental material, 6th ed. St. Louis, C.V. Mosby, 1980

^[8]Peck CC, Biomechanics of occlusion - implications for oral rehabilitation, J Oral Rehabil 2016;43(3):205-214

LEONE SURGICAL INSTRUMENTS ARE SUPPLIED NON-STERILE: CLEANING, DISINFECTION AND STERILIZATION AFTER REMOVAL FROM THE PACKAGE AND PRIOR TO EACH FURTHER USE ARE REQUIRED. CONSULT THE "Guidelines for Cleaning, Disinfection and Sterilization of reusable XCN® Leone instruments" AVAILABLE FOR DOWNLOAD AT www.leone.it IN THE SECTION Services/Quality.



The Surgical Procedure reported was conceived with the invaluable contribution of Dr. Leonardo Targetti, whom we thank sincerely.

Interactions between dental implant and medical imaging techniques

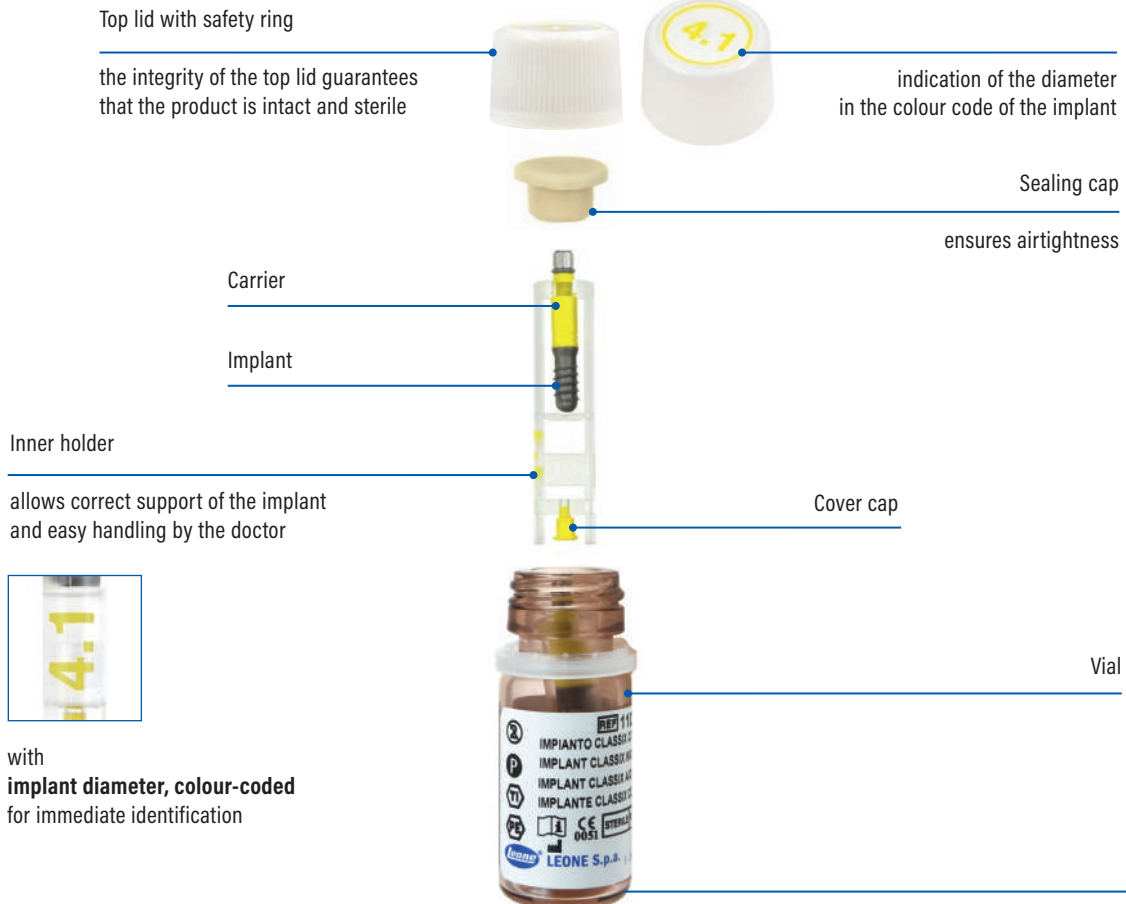
Titanium dental implants hardly cause pulling or heating sensation for the patient during Magnetic Resonance Imaging (MRI) and the artifacts on the bioimage are usually attributable to the implant-prosthetic device. For further details please refer to the document "Interactions between Leone orthodontic and implantology devices and medical imaging techniques" available for download at www.leone.it in the section **Services/Quality**.

XCN® IMPLANT PACKAGING

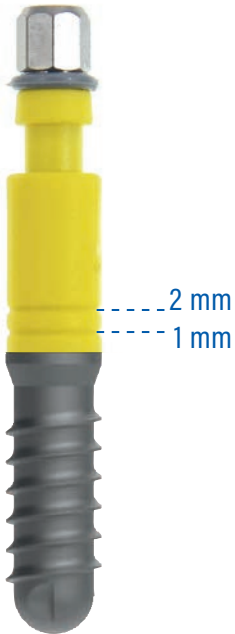
- double protection to preserve the sterility of the implant subjected to a certified gamma x-ray process
- 4 peel-off labels (2 with UDI Data Matrix) for:
 - the "Implant Card" to be delivered to the patient
 - the communication with the prosthetic team
 - the clinical case sheet of the patient
 - the inventory management
- with sterility indicator on the vial



STERILE BARRIER: VIAL



CARRIER FOR XCN® IMPLANTS



Pre-mounted on each XCN® implant

- it maintains the implant suspended within the inner holder and prevents contact with the glass vial and the sterile field
- it enables the secure transfer of the implant into the mouth

Colour-coded for instant identification

- the titanium core is covered by a biopolymer outer shell in the colour code of the implant

With depth indicators

- at 1 and 2 mm for better visibility when inserting the implant below the level of alveolar crest

With torque limiting device

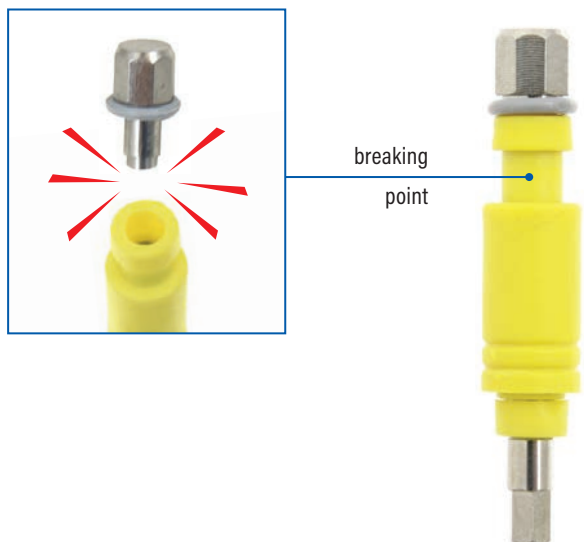
- the torque limiting device makes the carrier break above the connection with the implant at 60 Ncm and then permits the removal of the carrier

Easy removal

- it is removed together with the insertion device after implant placement

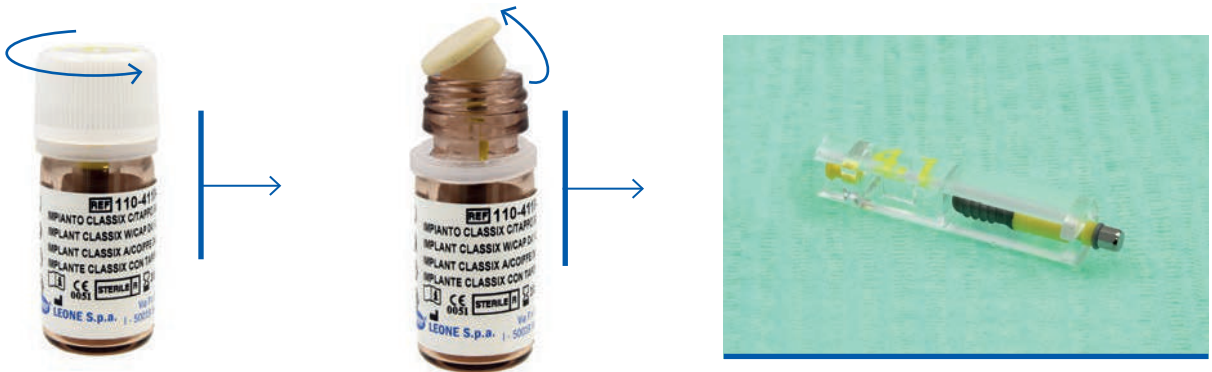
Suitable as paralleling pin

- it is possible to place the carrier again on the implant to check the parallelism with natural teeth and/or adjacent implant sites

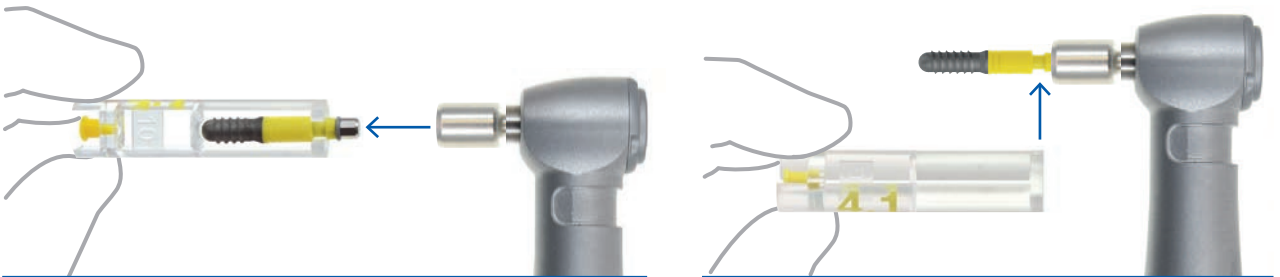


REMOVAL OF XCN® IMPLANT FROM THE VIAL

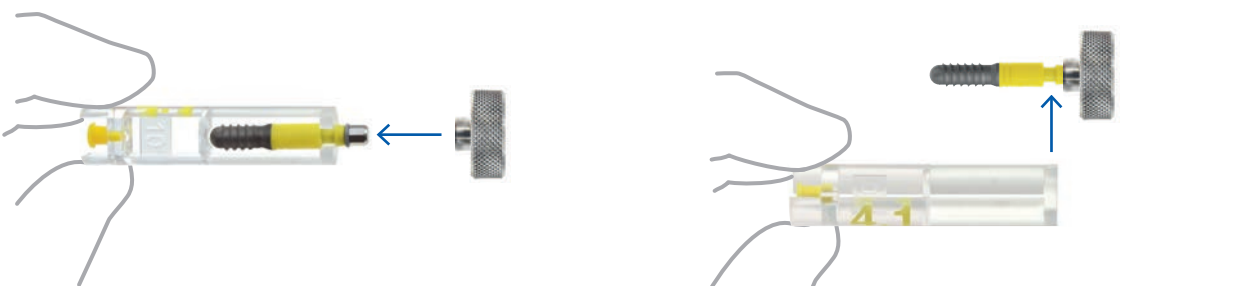
- open the vial's top lid and extract the inner holder with the implant and cover cap on a sterile pad



- connect the handpiece adapter to the carrier of the implant and remove the implant from the holder



- for a manual placement, connect the surgical hand screwdriver to the implant carrier and remove the implant from the holder



DRILLING DEPTH

- the length of the drill tip (max. 1 mm) is not included in the depth mark measurements on the pilot and twist drills



DEPTH STOPS FOR SHORT DRILLS

Mounting of depth stop:

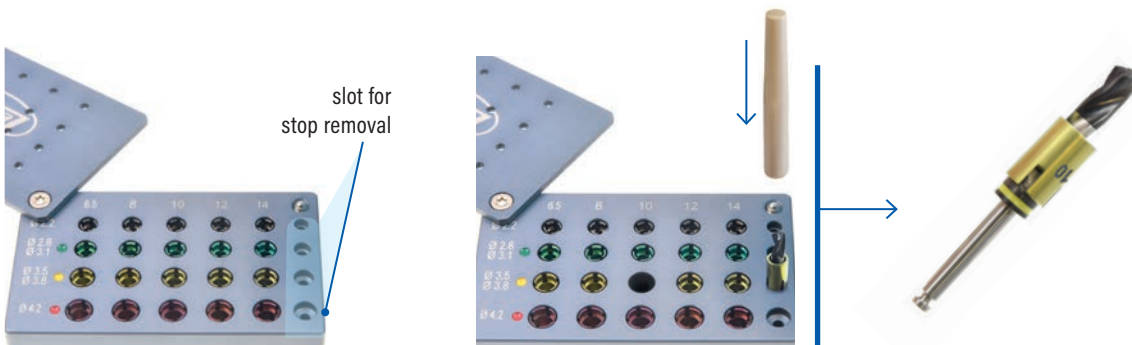
- insert the drill's tip into the hole of the drill stop kit corresponding to the diameter, the colour of the instrument and the selected depth
- push the drill all the way down to set the stop into position
- verify that the stop is positioned at the correct height

Note: if a stop loses stability, slightly tighten the clamping mechanism with tweezers



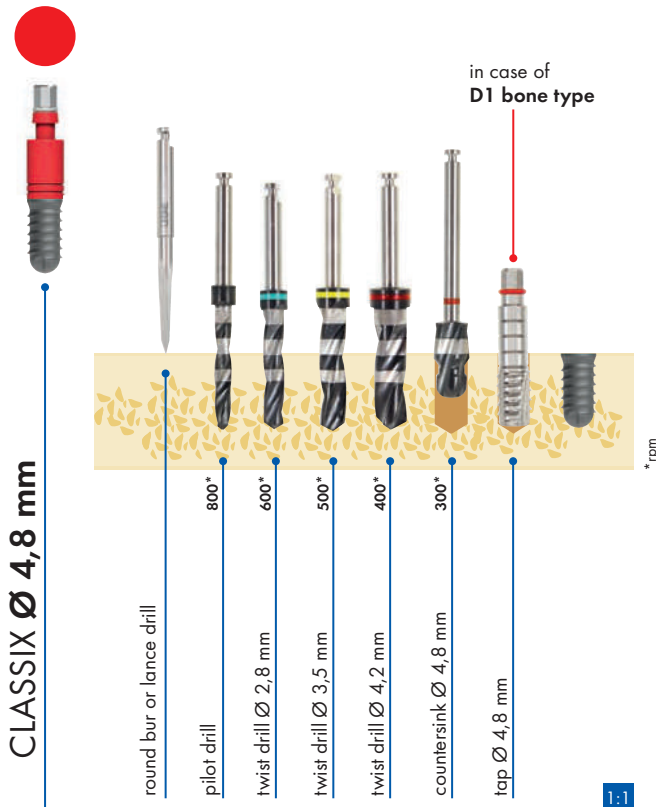
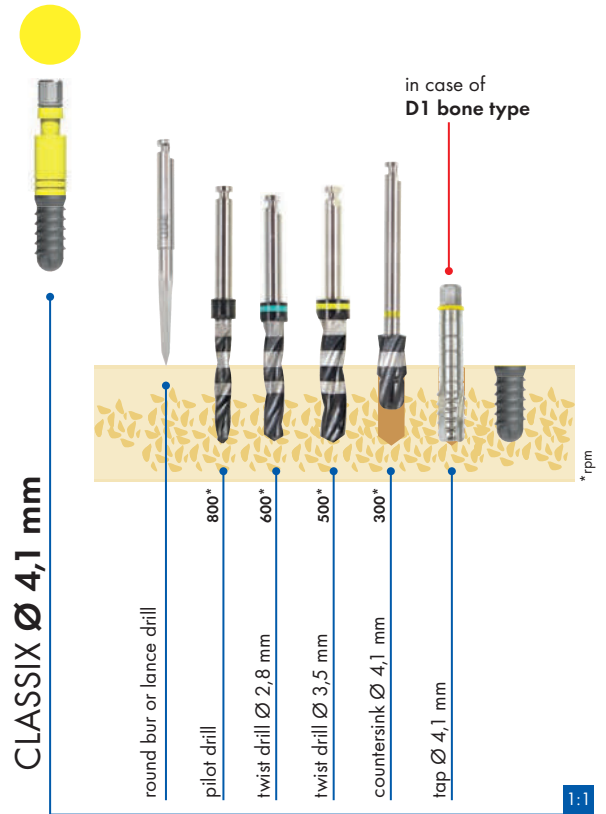
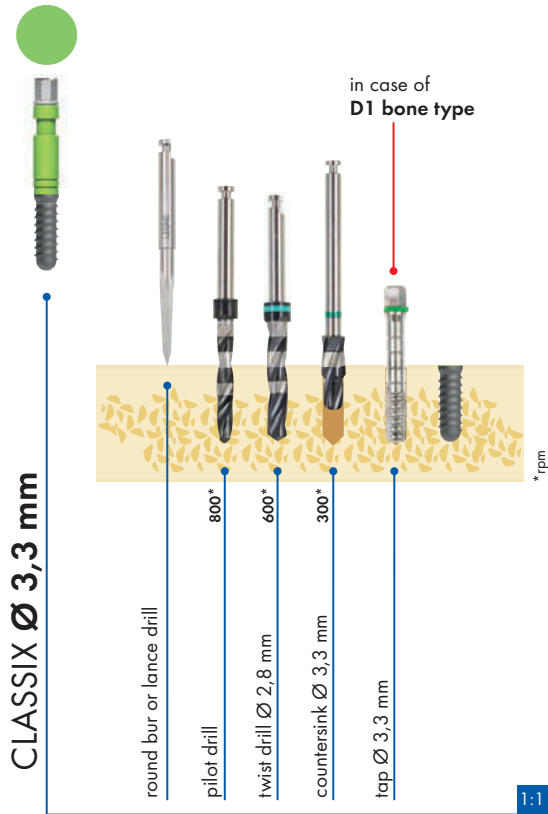
Removal of depth stop*:

- insert the drill shank into the specific slot of the drill stop kit corresponding to the diameter of the drill
- place the specific PEEK tool for stop removal onto the tip of the drill and push down to remove the stop



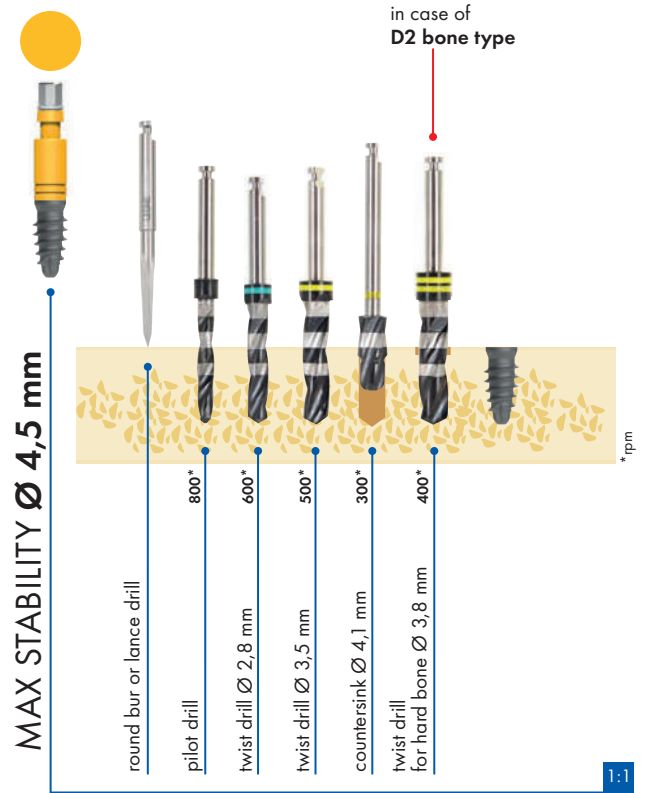
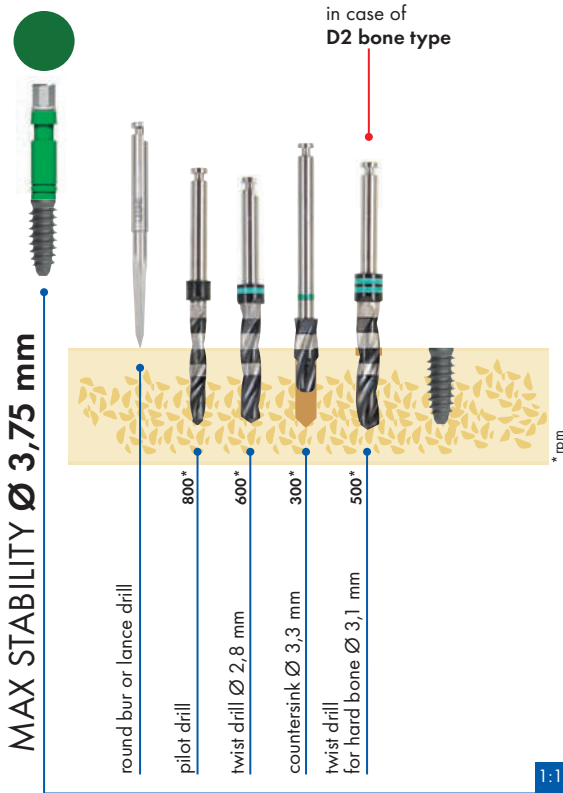
*Depth stops must be removed from the drills before cleaning, disinfection and sterilization.

DRILLING PROTOCOL FOR CLASSIX IMPLANTS



HIGH BONE DENSITY - D1 BONE TYPE:
- the use of the tap is recommended

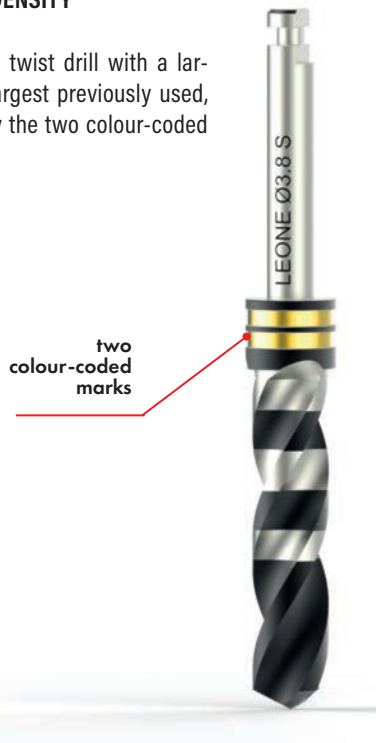
DRILLING PROTOCOL FOR **MAX STABILITY** IMPLANTS



Do not use Max Stability implants in thick cortical bone, equivalent to D1 bone type.

**MEDIUM-TO-HIGH BONE DENSITY
D2 BONE TYPE:**

- it is necessary to use a twist drill with a larger diameter than the largest previously used, easily distinguishable by the two colour-coded marks on the shank.

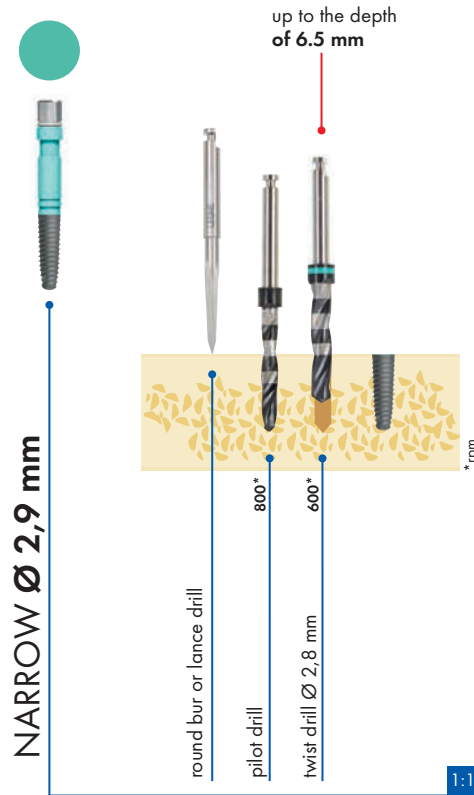


**FOR BETTER MAINTENANCE OF
IMPLANT SITE AXIS:**

- the use of the handpiece for the insertion of Max Stability implants is recommended.

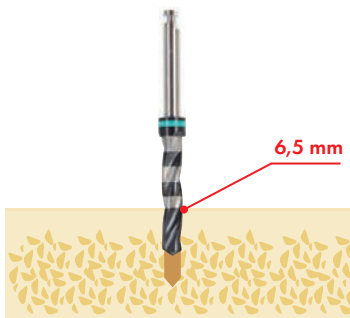


DRILLING PROTOCOL FOR 2.9 NARROW IMPLANTS



Ø 2,8 MM TWIST DRILL:

- use up to a depth of 6.5 mm for final sizing of the implant site. This depth is the same for all the three lengths of 2.9 Narrow implant.



HIGH BONE DENSITY - D1 BONE TYPE:

- it is necessary to use the Ø 2,8 mm twist drill up to 2 mm less than the length of the selected implant (e.g. implant L = 10 mm, drill up to a depth of 8 mm).

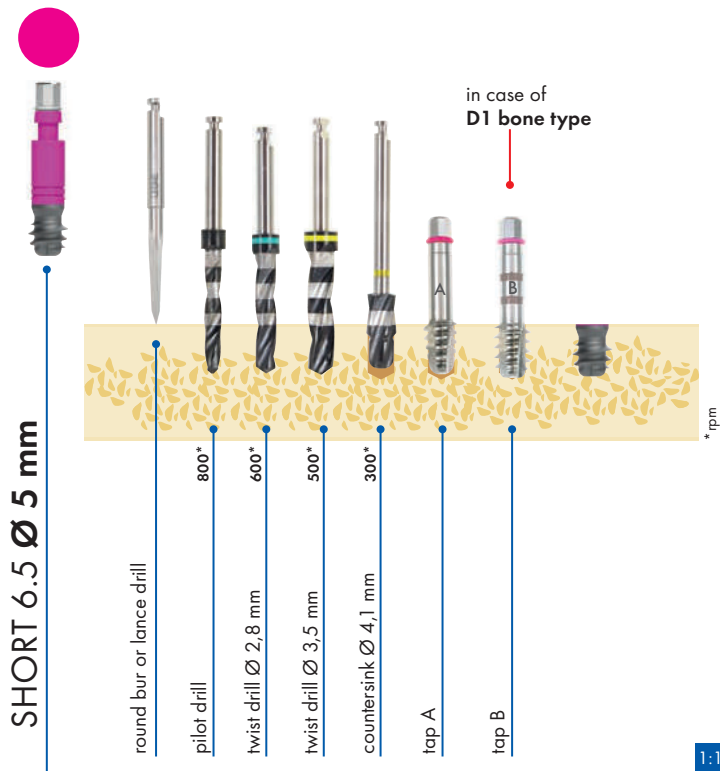


SUBCRESTAL IMPLANT PLACEMENT:

- use the Ø 3,3 mm countersink to allow a complete seating of the healing cap or the abutment.

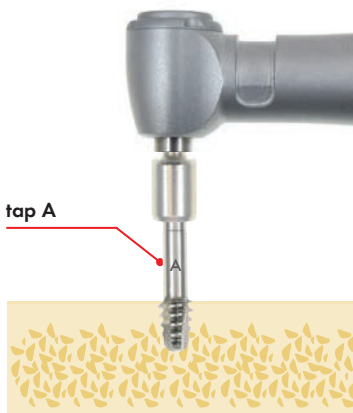


DRILLING PROTOCOL FOR **6.5 SHORT IMPLANT**



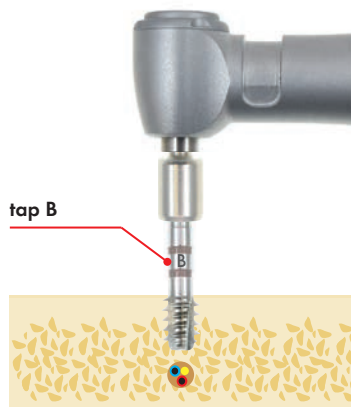
PRIOR TO PLACING A 6.5 SHORT IMPLANT:

- it is always necessary to use the tap "A" until the tap's threaded portion is totally inside the bone.



HIGH BONE DENSITY - D1 BONE TYPE:

- the use of tap "B" is necessary after tapping with bone tap "A". Use also tap "B" until the tap's threaded portion is totally inside the bone; tap "B" is easy distinguishable by the two marks on the shank.



FOR BETTER MAINTENANCE OF IMPLANT SITE AXIS:

- the use of the handpiece for tapping and insertion of 6.5 Short implant is recommended.

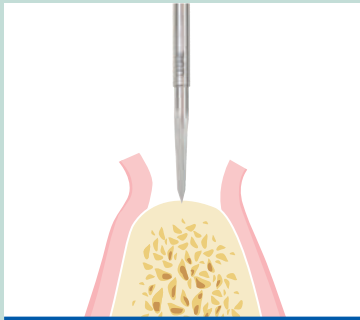


1. PREPARATION OF THE IMPLANT SITE: STEP-BY-STEP

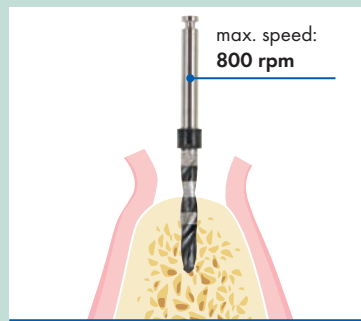
Illustrative protocol for **Classix Ø 4.1 L 10 mm implant**

NOTE:

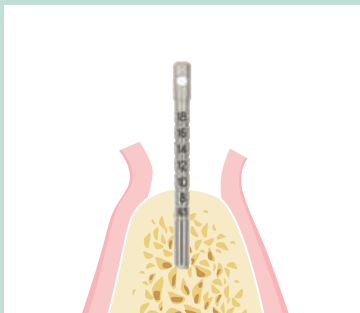
- the use of the drills must be accompanied by adequate irrigation;
- in case of a subcrestal implant placement, take into account the planned level of implant placement when calculating the drilling depth.



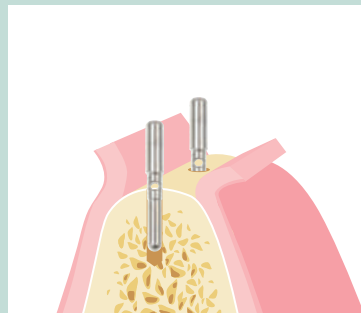
- Use the lance drill or round bur to mark the cortical bone for the subsequent drills.



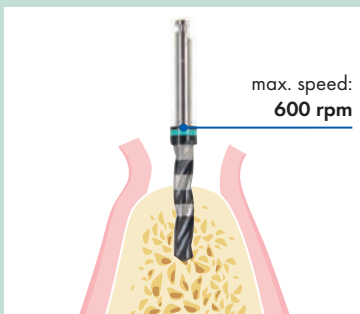
- Use the pilot drill up to the depth mark corresponding to the length of the selected implant.



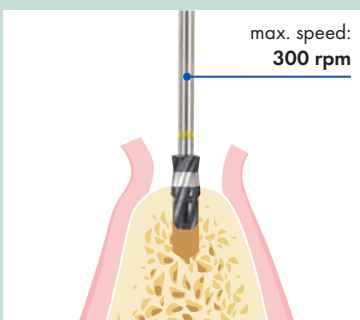
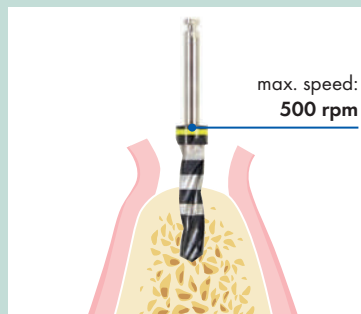
- Check the depth of the implant site with the depth gauge.



- Check parallelism with natural teeth and/or other adjacent implant sites with the paralleling pin. The paralleling pin can also be utilized after the application of the Ø 2,8 mm twist drill, taking care to seat the larger diameter in the implant site.

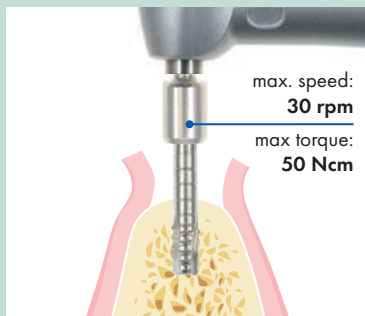


- Widen the diameter of the implant site with drills of increasing diameter. The drills have to be used up to the depth mark corresponding to the length of the selected implant.



- Use the countersink to shape the osteotomy for the flared coronal portion of the implant.

IN CASE OF HIGH BONE DENSITY

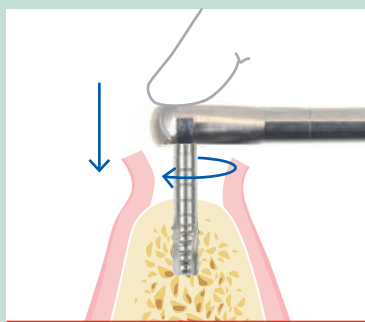
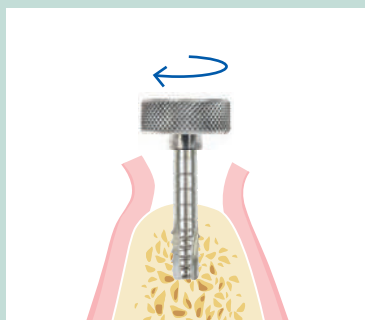


- In case of high bone density (D1 bone type), the use of the tap is recommended.

The tap can be connected either to the surgical hand screwdriver or to the handpiece.

If there is not enough space for a direct connection between the tap and the instruments, the extension for instruments may be used.

For use with a handpiece, connect the tap to the special adapter and set the micromotor to a max speed of 30 rpm and a max torque value of 50 Ncm.



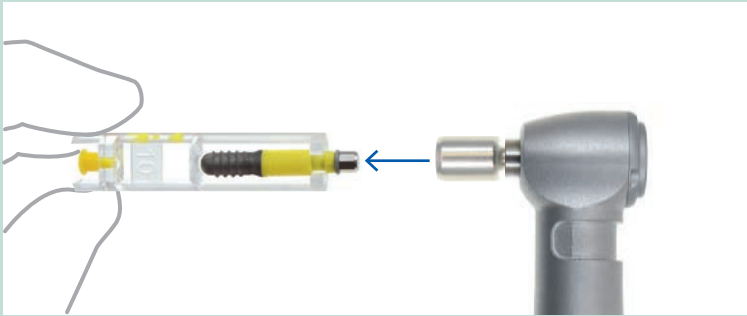
- Use the ratchet if the maximum torque value is not enough to complete tapping.

2. PLACEMENT OF THE IMPLANT: STEP-BY-STEP

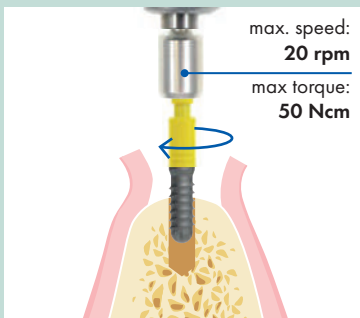
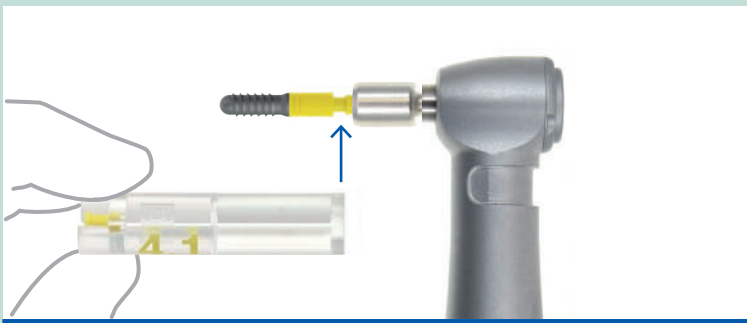
Illustrative protocol for **Classix Ø 4.1 L 10 mm implant**

NOTE:

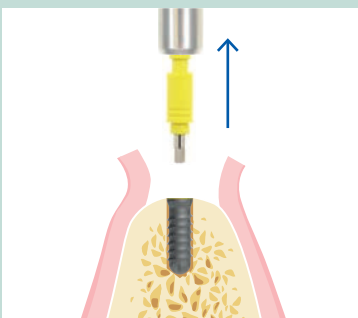
- the Classix implant can be screwed in with the help of the handpiece or of the surgical hand screwdriver; the use of the contra-angle handpiece ensures the maintenance of the implant site axis while driving the implant into the surgical cavity;
- insert the implant without irrigation.



- Connect the handpiece adapter to the carrier of the implant and extract the implant from the holder. If there is not enough length with the carrier and adapter to reach the implant site, the extension for instruments may be used.

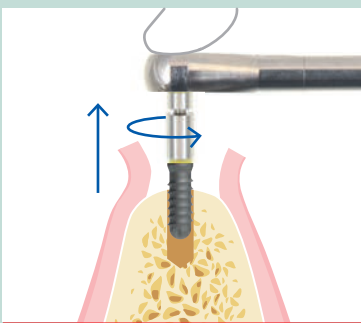
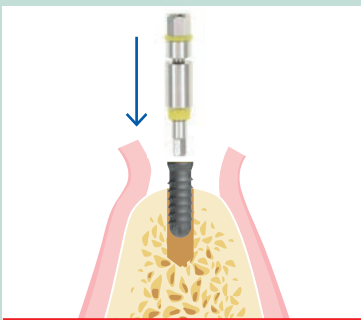
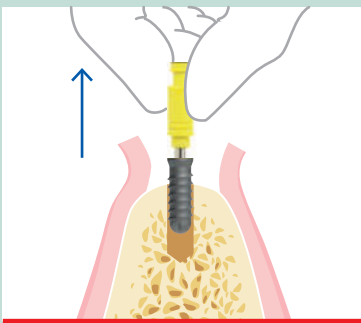
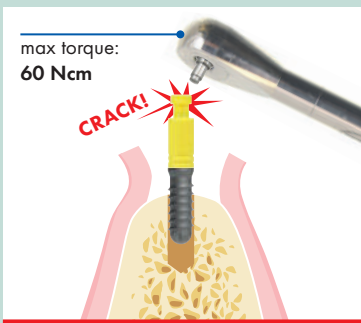
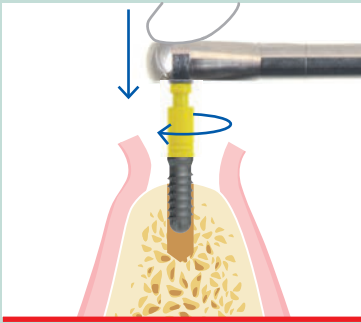


- Set a micromotor's maximum speed to 20 rpm and a max. torque value to 50 Ncm.
- Insert the implant up to the prepared level.



- Remove the carrier from the implant by pulling it out.

IF IMPLANT INSERTION IS DIFFICULT



- If the pre-set maximum torque value is not sufficient to complete implant insertion, remove the handpiece adapter from the carrier and attach the ratchet. It is recommended to keep the instrument well aligned by keeping a finger on the head of the instrument, avoiding flexion.

- When using a ratchet, the forces exerted on the implant and the correspondent periimplant bone can become excessive. In this eventuality, should a value of 60 Ncm be exceeded, a torque limiting device makes the carrier break above the connection with the implant and then the carrier can be removed.

Note that carrier fracture is not always visible, but it is detectable by a sudden loss of functionality of the insertion instrument accompanied by a sharp crack.

- If fractured, remove the carrier.

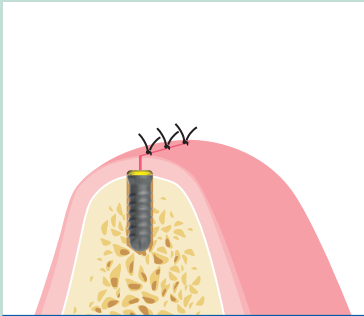
- Replace the carrier with the High Torque driver for 3.0 connection which withstands torque values up to 160 Ncm.

- Attach the ratchet to the driver and remove the implant from the implant site.

- Tap the site and place the implant again.

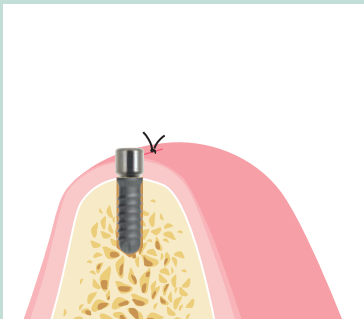
3. HEALING OPTIONS

After implant placement, it is possible to choose among several healing options:



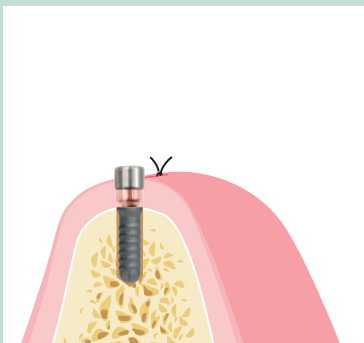
3.1

**TWO-STAGE TECHNIQUE
WITH COVER CAP**
supplied with the implant package



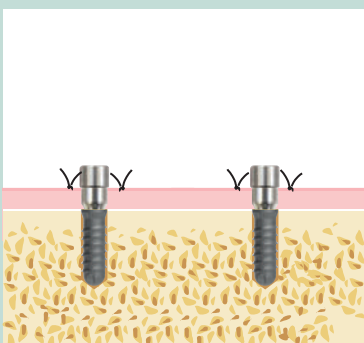
3.2

**ONE-STAGE TECHNIQUE
WITH HEALING CAP**



3.3

**TRANSGINGIVAL HEALING
WITH EXACONNECT PLUS**
(if a single-unit screw-retained restoration is planned)



3.4

**TRANSGINGIVAL HEALING
WITH MUA PLUS**
(if a multi-unit screw-retained restoration is planned)

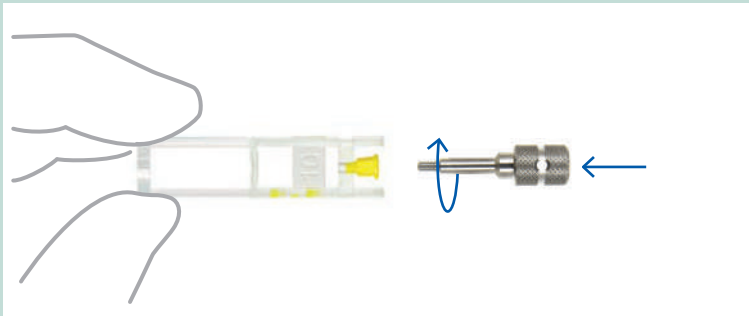


As an alternative, after a thorough evaluation by a clinical expert, it is possible to opt for an immediate loading procedure.

3.1 TWO-STAGE SURGICAL PROCEDURE: FIRST STAGE

NOTE:

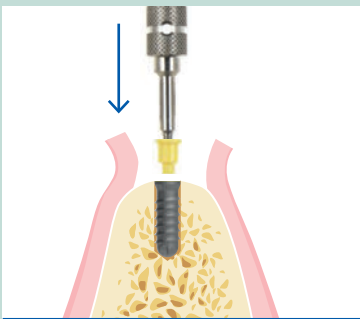
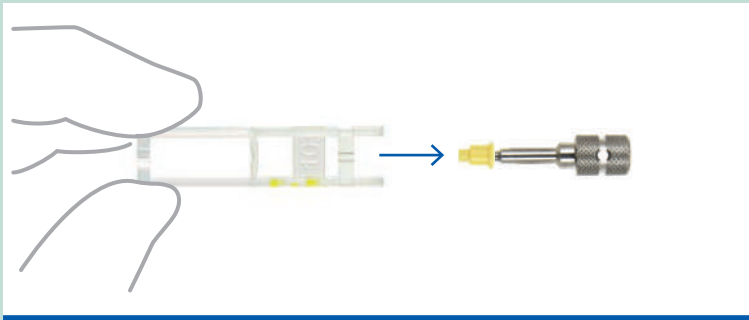
- if you have planned a subcrestal implant placement, use a GH 1.5 healing cap instead of the cover cap included in the implant package, to avoid bone growth on the cap.



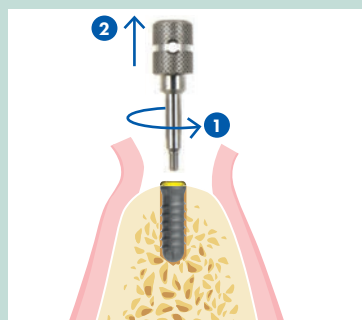
- Take the holder that previously contained the implant.

- Screw the instrument for cover caps onto the head of the cover cap.

Remove the biopolymer cover cap from the holder with a gentle extraction.

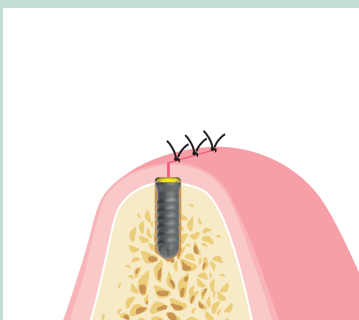


- After rinsing and drying of the inner part of the implant, insert the cap into the implant and press down.



- Unscrew the instrument for cover caps.

- Press on the cap with a blunt instrument to make sure it is pushed all the way down.

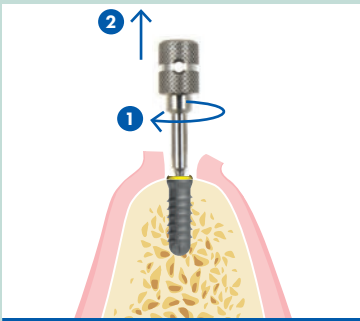


- The soft tissue is sutured over the implant.

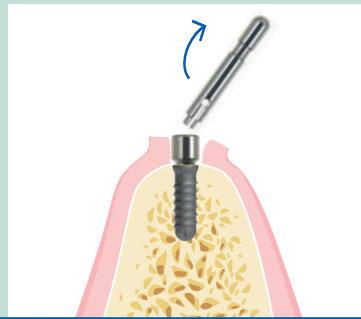
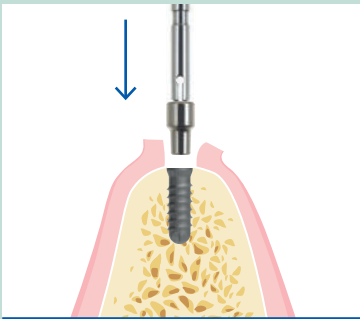
3.1 TWO-STAGE SURGICAL PROCEDURE: SECOND STAGE

NOTE:

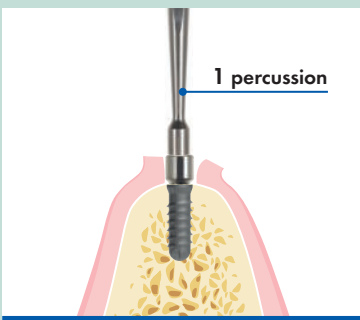
- select the healing cap according to the connection diameter (\varnothing 2,2 mm green, \varnothing 3,0 mm yellow), the gingival thickness and the prosthetic platform diameter.



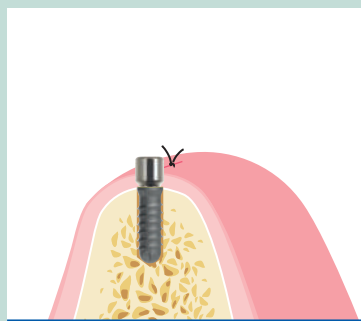
- Once osseointegration has occurred, make an incision to expose the implant and remove the cover cap with the specific instrument for cover caps.
- Screw the instrument for cover caps onto the head of the cover cap and remove by pulling it out.
- Rinse and dry the inner part of the implant.



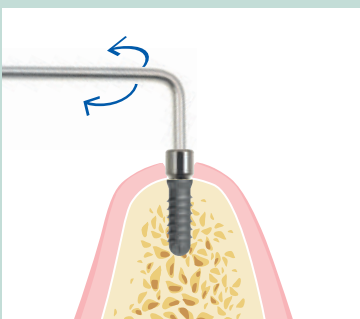
- Open the vial and extract the inner holder containing the sterile healing cap mounted on the carrier.
- Place the cap into the implant and exert a pressure on the carrier.
- Remove the carrier with a gentle side bending.



- Activate the locking-taper connection by applying a percussive force. We recommend to perform **1 percussion** with the specific abutment seater with titanium tip (with the abutment seater Double Force, use the HALF slot).



- Suture the soft tissues around the healing cap.



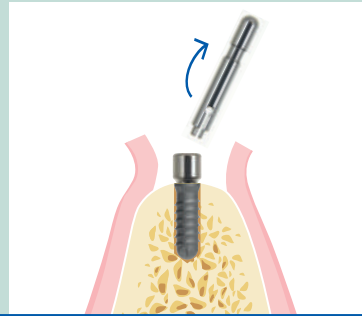
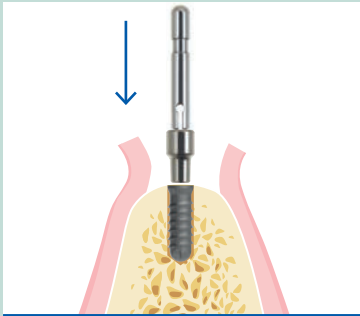
- When the healing process has occurred, unlock the healing cap by means of the specific hex head extractor.
- Seat the extractor into the hexagon on the head of the healing cap and rotate either clockwise or counter clockwise to unlock the healing cap.
- Use tweezers to remove the cap from the implant.

For impression taking and the fabrication of the prosthesis, refer to the "Prosthetic procedure" page 123

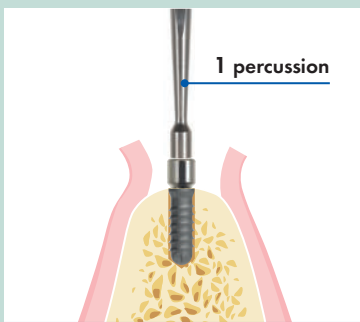
3.2 ONE-STAGE SURGICAL PROCEDURE

NOTE:

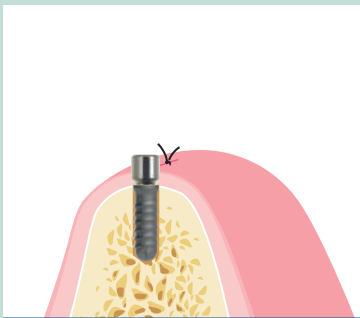
- select the healing cap according to the connection diameter (\varnothing 2,2 mm green, \varnothing 3,0 mm yellow), the gingival thickness and the prosthetic platform diameter of the abutment;
- in case of flapless procedure and subcrestal implant placement, use Standard healing caps.



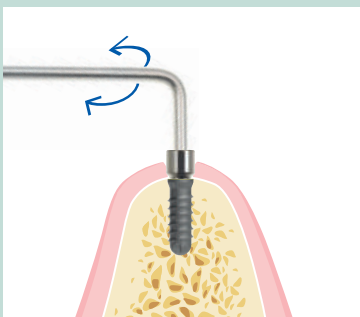
- Rinse and dry the inner part of the implant.
- Open the vial and extract the inner holder containing the sterile healing cap mounted on the carrier.
- Place the cap into the implant and exert a pressure on the carrier.
- Remove the carrier with a gentle side bending.



- Activate the locking-taper connection by applying a percussive force. We recommend to perform **1 percussion** with the specific abutment seater with titanium tip. (with the abutment seater Double Force, use the HALF slot).



- Suture the soft tissues around the healing cap.



- When the osseointegration has occurred, unlock the healing cap by means of the specific hex head extractor.
- Seat the extractor into the hexagon on the head of the healing cap and rotate either clockwise or counter clockwise to unlock the healing cap.
- Use tweezers to remove the cap from the implant.

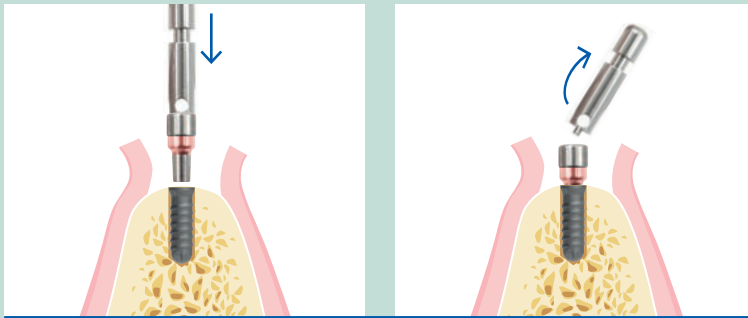
For impression taking and the fabrication of the prosthesis, refer to the "Prosthetic procedure" page 123

3.3 TRANSGINGIVAL HEALING WITH EXACONNECT PLUS

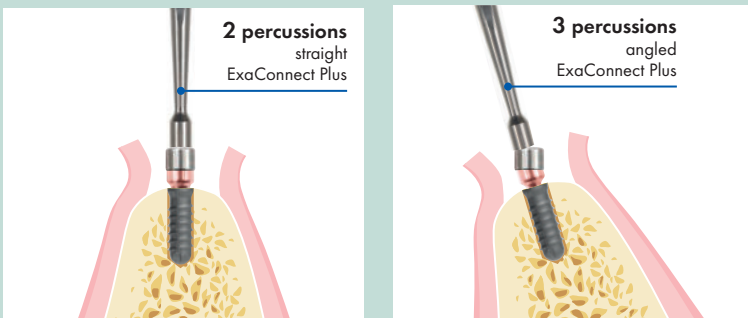


NOTE:

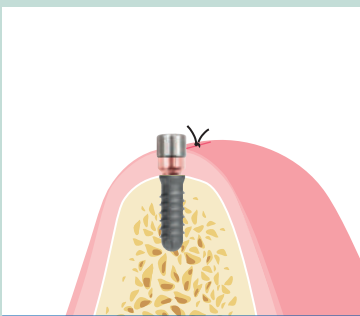
- select the ExaConnect Plus according to the connection diameter (\varnothing 2,2 mm green, \varnothing 3,0 mm yellow);
- use the Abutment Gauges to choose the most suitable ExaConnect Plus in terms of GH and angulation;
- ExaConnect Plus with green connection (\varnothing 2,2 mm) has a \varnothing 4,1 mm prosthetic platform; therefore in case of >1 mm subcrestal implant placement use the \varnothing 4,5 mm Bone Profiler to allow the complete seating of the ExaConnect Plus.



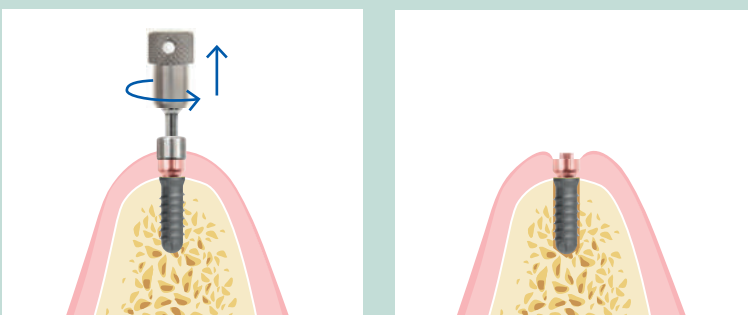
- Rinse and dry the inner part of the implant.
- Open the vial and extract the inner holder containing the sterile ExaConnect Plus with its healing screw mounted on the carrier.
- Place the ExaConnect Plus into the implant and rotate the connector to find the correct position.
- Exert a pressure on the carrier. Remove the carrier with a gentle side bending.



- Place the specific abutment seater with titanium tip on the healing screw pre-mounted on the ExaConnect Plus.
- In order to activate the locking-taper connection perform:
2 percussions onto the straight ExaConnect Plus
3 percussions onto the angled ExaConnect Plus
 (by aligning the instrument along the implant axis).



- Suture the soft tissues around the ExaConnect Plus.



- When the osseointegration has occurred, unscrew the healing screw by means of the specific adapter for screws mounted on the prosthetic hand screwdriver.

The ExaConnect remains in place.
The impression taking and the restoration will be done on the ExaConnect.

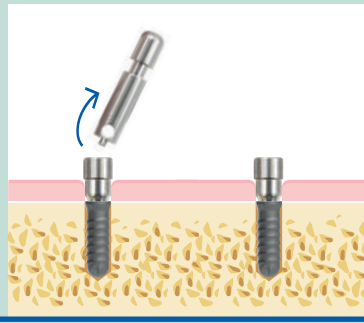
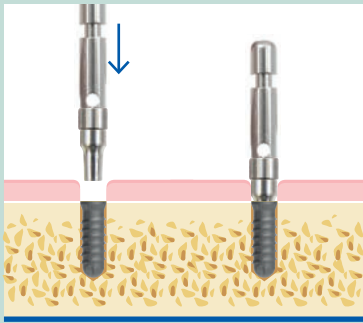
For impression taking and the fabrication of the prosthesis, refer to the "Prosthetic procedure" page 123

3.4 TRANSGINGIVAL HEALING WITH MUA PLUS

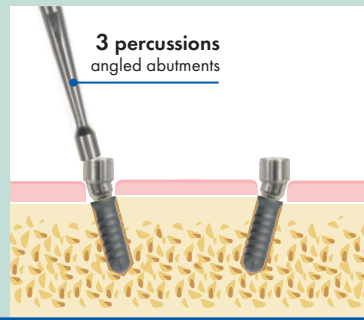
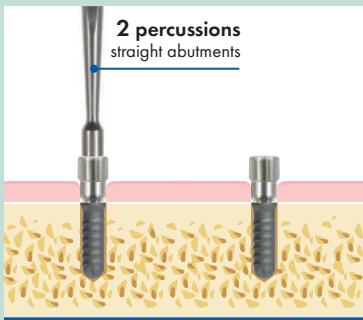


NOTE:

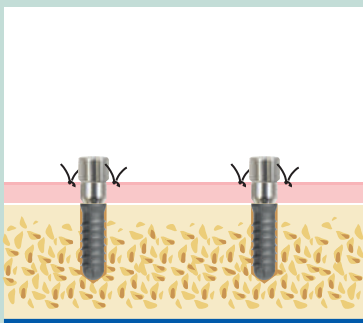
- select the MUA Plus according to the connection diameter (Ø 2,2 mm green, Ø 3,0 mm yellow);
- use the Abutment Gauges to choose the most suitable MUA Plus in terms of GH and angulation.



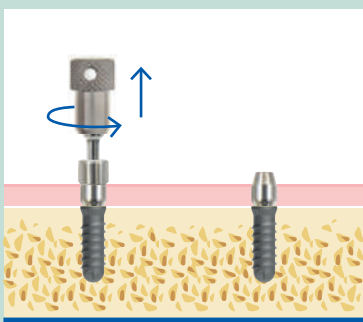
- Rinse and dry the inner part of the implant.
- Open the vial and extract the inner holder containing the sterile MUA Plus with its healing screw mounted on the carrier.
- Place the MUA Plus into the implant and rotate to find the correct position.
- Exert a pressure on the carrier.
Remove the carrier with a gentle side bending.



- Place the specific abutment seater with titanium tip on the healing screw pre-mounted on the MUA Plus.
- In order to activate the locking-taper connection perform,
2 percussions onto straight abutments
3 percussions onto angled abutments
(by aligning the instrument along the implant axis).



- Suture the soft tissues around the MUA Plus.



- When the osseointegration has occurred, unscrew the healing screw by means of the specific short adapter for screws mounted on the prosthetic hand screwdriver.
- The MUA remains in place.
The impression taking and the restoration will be done on the MUA.

For impression taking and the fabrication of the prosthesis, refer to the "Prosthetic procedure" page 123