SURGICAL

procedure

2015

for

Leone

implant system

Proc. 01/10-12 *May 01, 2015*

DISCLAIMER

The Surgical Procedure and the use of the products of the 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 **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
Implant therapy is indicated in the treatment of the following conditions:
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.

PREOPERATIVE 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 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 with a first evaluation of the bone morphology and thickness.
• a complete periodontal probing for the appraisal of the absence of both gengivitis 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 enables to appraise 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: 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 computerized tomography 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 seated 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.

Templates (page 39) are available showing all **LEONE** implants in actual dimensions, with dimensions increased by 10% and increased by 25%, to match possible distortions created by the instrument for radiographic examinations (CT, panoramic radiograph, standard and digital cephalograms). Superimpose the template to the radiograph in order to select the implant in relation to the quantity of bone available.

Do not *seat a single Ø 3.3 mm implant in molar position.*
The Ø 3.3 mm implant, length 8 mm, must be used as a supplementary implant in the prosthesis composed of two or more implants of any diameter and length.
The ***LEONE 6.5*** *short implant is intended for use only in cases with limited vertical bone availability. It is not intended to be associated with sinus lift procedures.*
Do not place the ***LEONE*** *implants above the level of the alveolar crest.*

The **LEONE** implant system is characterized by a high mechanical resistance validated through fatigue strength testing according to the ISO 14801 international standard, which indicates to perform testing with a cyclic loading at an angle of 30° with respect to the implant-abutment axis. For the **LEONE** implants of minor diameter, and thus the most relevant ones, the results are: Ø3,3 mm and Ø3,75 mm implant fatigue strength: 240 N; Ø4,1 mm, Ø4,5 mm and **LEONE 6.5** short implant fatigue strength: 392 N.[1,2]
In the literature, in comparison, it is reported that the average force generated during mastication is 145 N with inclinations up to 10°.[3 4] It should also be underlined that very high masticatory forces[5] 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.

[1] ISO 14801:2007 (E), Dentistry - Implants - Dynamic fatigue test for endosseous dental implants, International Organization for Standardization, Geneva, 2007
[2] 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
[3] Carlsson GE, Haraldson T. Functional response. In: Branemark P-1. Zarb GA, Albrektsson T. Eds. Tissue integrated prostheses. Osseointegration in clinical dentistry. Chicago: Quintessence, 1985:155-63
[4] 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
[5] Craig RG. Restorative dental material. 6th ed. St. Louis, C.V. Mosby, 1980

SURGICAL KIT AND ORGANIZER

The surgical kit, (page 40), completely autoclavable, contains all the necessary surgical instruments for the implant treatments with the **LEONE** Implant System.

To simplify the surgical operation, a surgical kit with reduced dimensions, an organizer (pages 42-44) was conceived by **LEONE** to sterilize and hold the necessary instruments on the operation field.
The organizer is fully autoclavable and it can contain up to 8 instruments on colour coded special supports.

Either the organizer or the surgical kit must be wrapped and sterilized before use.
The sterilization must be done as follows:
- wrap the organizer or the kit into a sterilization bag as requested by the manufacturer of the sterilizing machine;
- autoclave at 121° (250°F) for 20 minutes;
- remove the organizer from the autoclave and leave it cool inside the bag;
- leave the organizer or the kit inside the bag to preserve sterility.

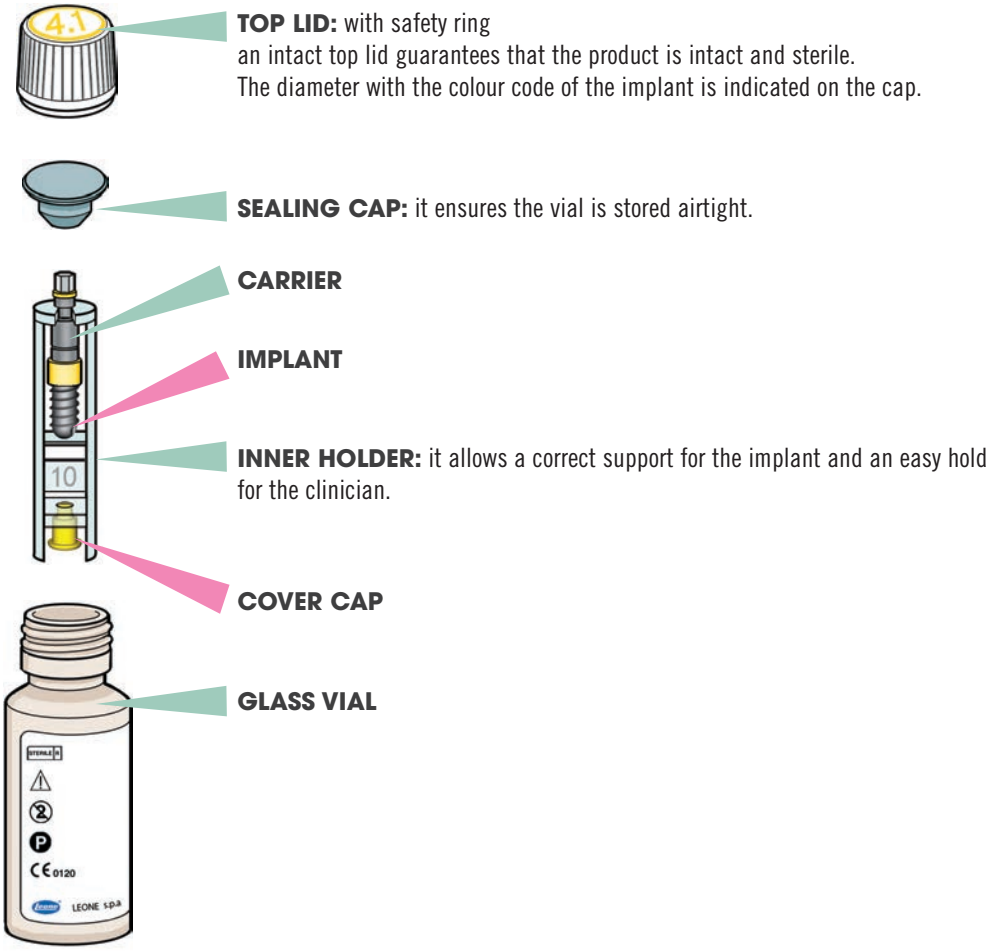
The Surgical Procedure and the Prosthetic Procedure reported were conceived with the invaluable contribution of Dr. Leonardo Targetti, whom we thank sincerely.

LEONE IMPLANT PACKAGING

THE PACKAGING

The packaging features a double protection to preserve the sterility of the implant subjected to a certified gamma x-ray process. A removable part of the label showing the information of the implant (see label symbols at page 125) is to be applied on the "Identity card" of the implant or on the clinical case sheet of the patient. A sterility indicator is present on the glass vial.

THE GLASS VIAL



TOP LID: with safety ring
an intact top lid guarantees that the product is intact and sterile.
The diameter with the colour code of the implant is indicated on the cap.

SEALING CAP: it ensures the vial is stored airtight.

CARRIER

IMPLANT

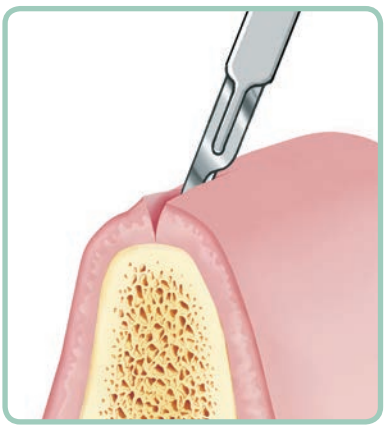
INNER HOLDER: it allows a correct support for the implant and an easy hold for the clinician.

COVER CAP

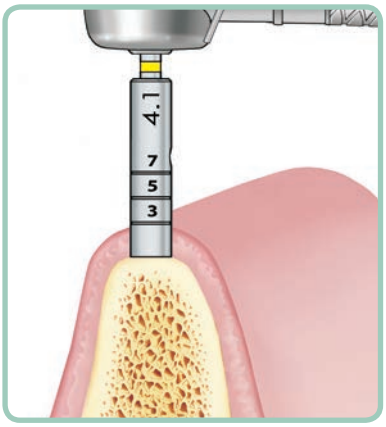
GLASS VIAL

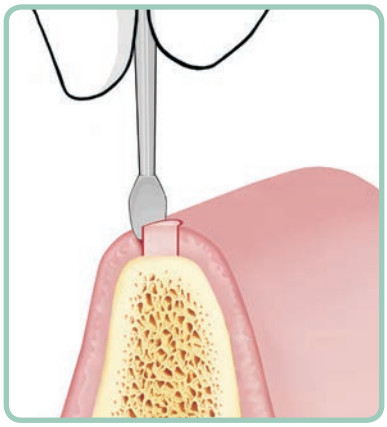
1) LEONE IMPLANTS Ø 3,3 - 4,1 - 4,8: PREPARATION OF THE IMPLANT SITE

The typology and the access to the surgical site shall be selected by the professional according to the clinical-morphological parameters. Schematically and with illustrative purpose only, the following steps for the preparation of the implant site are illustrated.

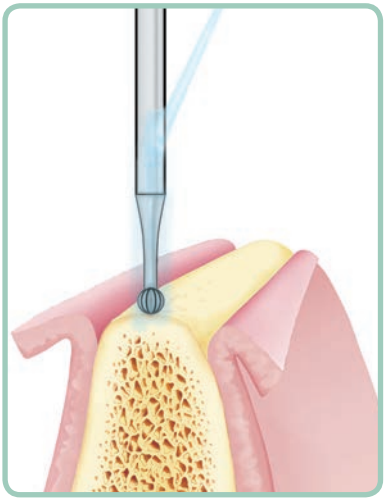


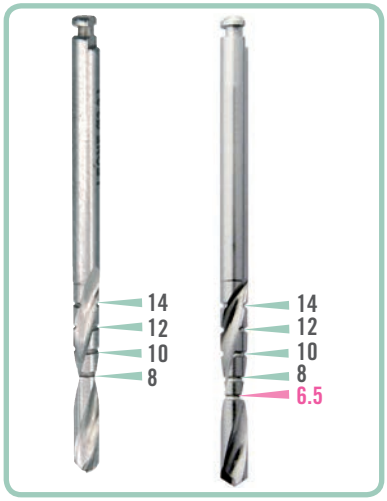
1.1a Make full-thickness incision of the soft tissues and detachment of the gingival flaps to have access to the bone ridge.





1.1b If flapless procedure is followed, use the mucosa punch for contra-angle of the same diameter of the implant. Set the handpiece to low speed (approx. 40 rpm). Use until bony tissue is met. To determine the gingival thickness around the implant area, the three black lines clearly visible around the mucosa punch, at the heights of 3-5-7 mm, starting from the crest bone, may be used. Remove the tissue plug by using a small periosteal elevator.





1.2 Use of the round bur Cat. 151-1934-01 to mark the cortical bone for the subsequent drills. Alternatively, it is possible to use the lance drill Cat. 151-1930-02, which is particularly suitable in case of narrow knife-edged ridges.

1.3 Prior to using any pilot or twist drill, it is important to check the number of the marks on the body of each drill:
- drills with 4 marks: 8 – 10 – 12 – 14 mm
- drills with 5 marks: 6.5 – 8 - 10 – 12 – 14 mm

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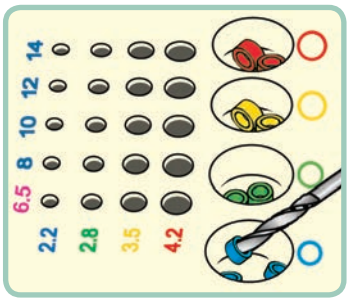
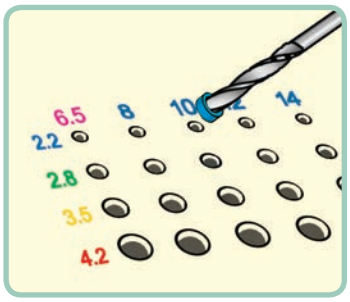
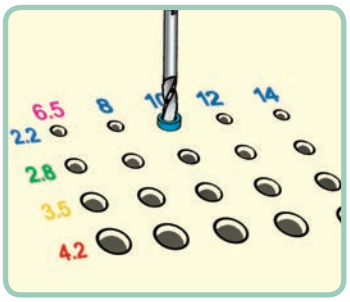
The use of the depth indicators is recommended to better visualize the drilling depth. The depth indicators are made of elastomer, for single use, manufactured in the colour code related to each implant diameter.
The depth indicators and the special positioner (Cat. 151-0001-00 page 30), available either in the kit or single supplied, must be sterilized in the autoclave before use. Choose the elastomer ringlet matching the diameter of the drill to be used (Ø 2.2 mm pilot drill, blue colour, Ø 2.8 mm twist drill, green colour, Ø 3.5 mm twist drill, yellow colour, Ø 4.2 mm twist drill, red colour).



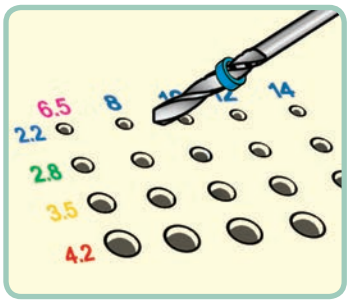
1.4 Seat the ringlet on the tip of the drill.



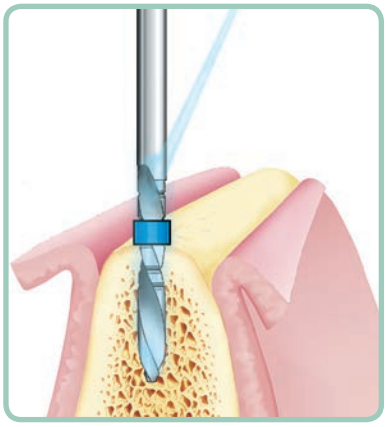
1.5 Placement of the drill into the hole corresponding to the diameter of the instrument and the selected depth.



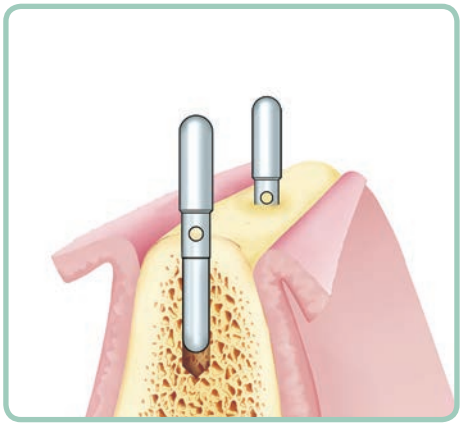
1.6 Push the drill all the way to the stop.



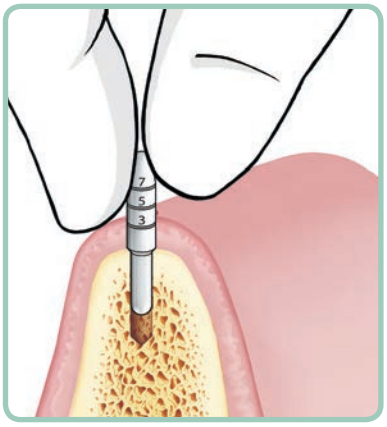
1.7 In this way the depth indicator will be driven into position with the corresponding mark for the selected depth.



1.8 Use of the Ø 2,2 mm pilot drill: drill up to the depth mark corresponding to the length of the selected implant.
(Max speed: 800 rpm with adequate irrigation)



1.9a Use of paralleling pins for the control of parallelism with natural teeth and/or other adjacent implant sites. A radiographic exam can be performed to increase accuracy in the evaluation of parallelism. The paralleling pin can also be utilized after the application of a Ø 2.8 mm twist drill, taking care to seat the pin in the implant site from the side with larger diameter. Paralleling pins present a hole for the placement of a safety leash.



1.9b With flapless procedure, use of measuring pin for gingival height for the control of the mucosa height and parallelism with natural teeth and/or other adjacent implant sites. Measuring pins for gingival height present a hole for the placement of a safety leash.

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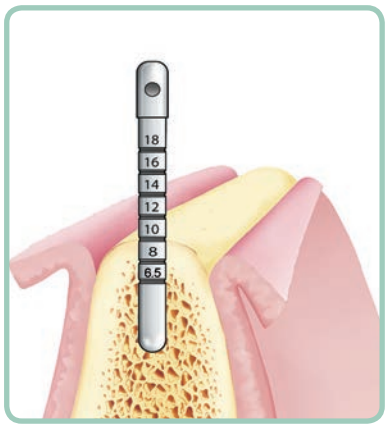
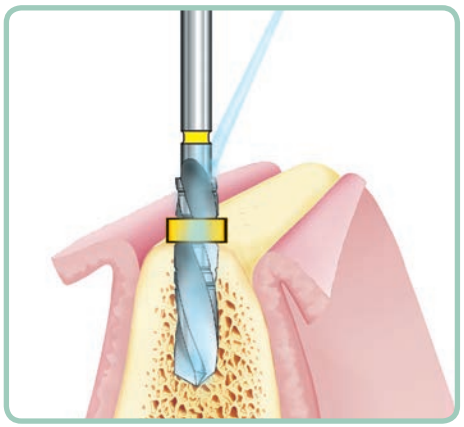
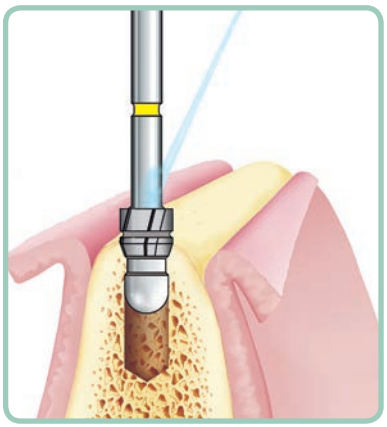


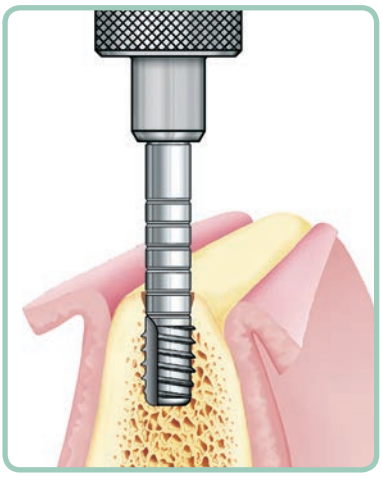
1.10 Use of the depth gauge to check the depth of the newly-created implant site. The depth gauge presents a hole for the placement of a safety leash.



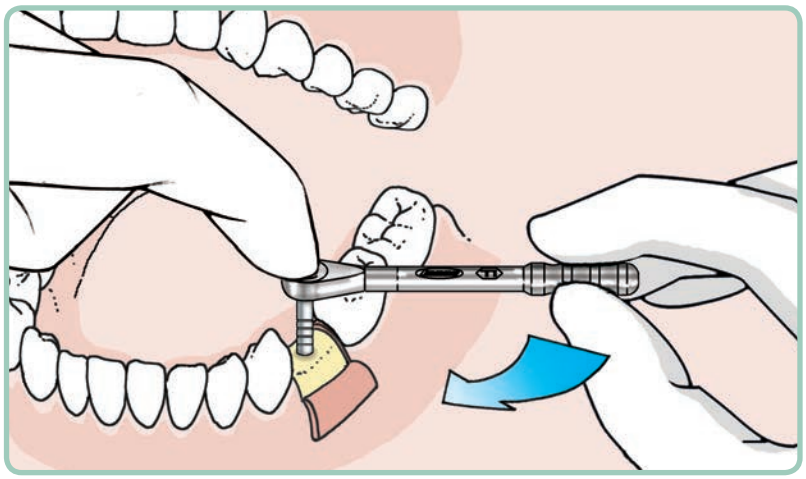
1.11 Widening of the diameter of the implant site with the progressive use of drills with increasing diameter. The drills have to be used up to the depth mark which corresponds to the length of the selected implant:
• **for Ø 3.3 mm implants**: use Ø 2.8 mm drill.
Max speed: 600 rpm.
• **for Ø 4,1 mm implants**: after Ø 2.8 mm drill, use the Ø 3,5 mm drill for the final resizing of the site. Max speed: 500 rpm.
• **for Ø 4,8 mm implants**: after using Ø 2.8 mm and Ø 3.5 mm drills, use the Ø 4.2 mm drill for the final resizing of the site. Max speed: 400 rpm.
Reminder: use adequate irrigation.



1.12 At the end of the widening operations of the implant site with the twist drills, the use of a countersink with the same diameter as the selected implant is recommended, by inserting it up to the reference mark. (Max speed: 300 rpm with adequate irrigation)



1.13 In case of high bone density, the use of the tap is recommended.
With medium/low bone quality the **LEONE** implant is self-tapping.



1.14 The tap can be connected either to the hand screwdriver or to the ratchet.
When the space for the direct connection between the tap and the instruments is insufficient, the extension Cat. 156-1002-00 can be utilized. Tapping operations may be also performed by means of a handpiece for implantology connecting the tap to the special adapter Cat. 156-1002-01. Set the handpiece to a max speed value of 30 rpm and a max torque value of 50 Ncm.

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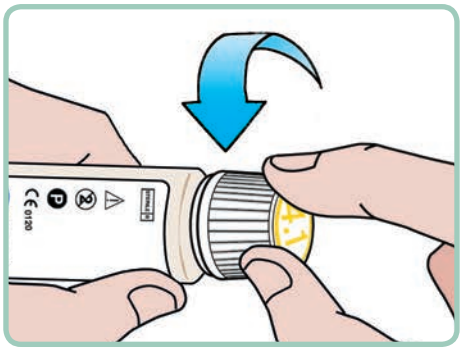
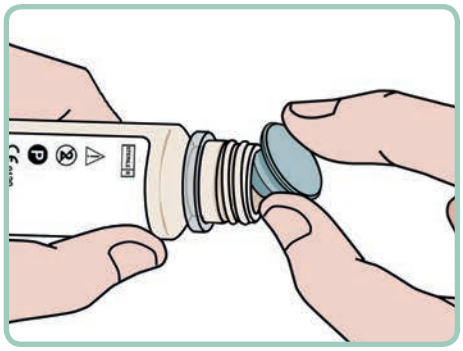
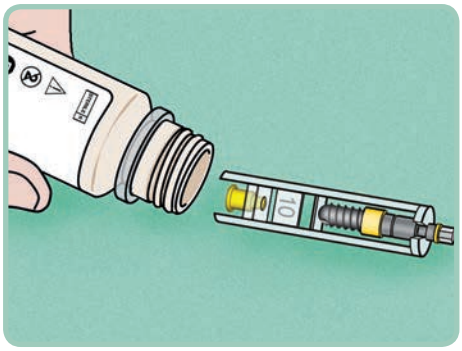
2) LEONE IMPLANTS Ø 3,3 - 4,1 - 4,8: PLACEMENT OF THE IMPLANT



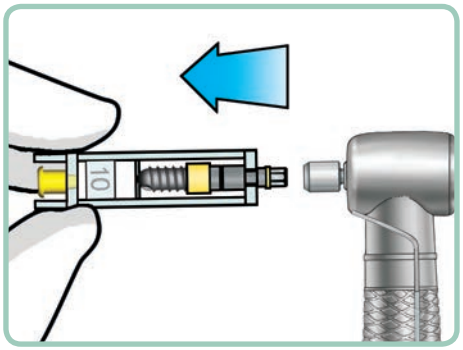
2.1 Unscrew the glass vial's top lid.



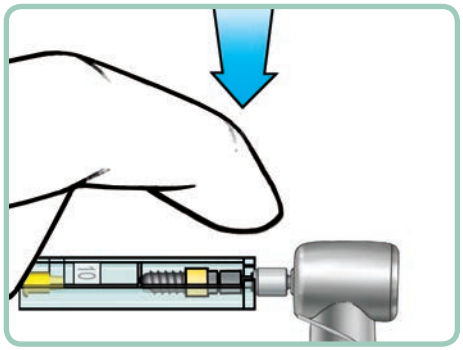
2.2 Remove the sealing cap.

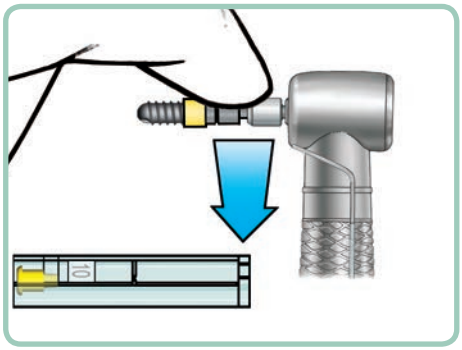


2.3 Extraction of the holder containing the implant and the cover cap on a sterile pad. The implant can be placed either with the handpiece or manually.

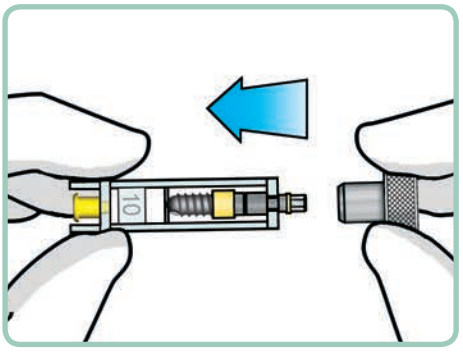


2.4a Connection of the handpiece adapter Cat. 156-1002-01 to the carrier of the implant. The use of the handpiece ensures the maintenance of the implant site axis.

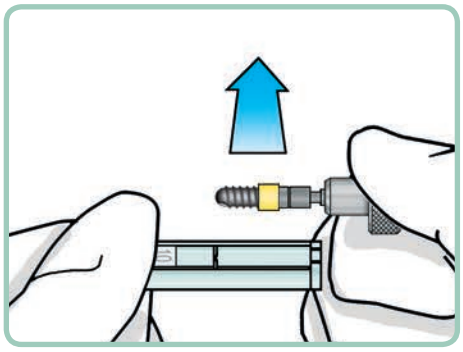




2.5a Extraction of the implant from the holder by exerting a pressure on the open side in order to detach the implant and make the holder fall down.



2.4b Connection of the hand screwdriver to the carrier of the implant. The hand screwdriver presents a hole for the placement of a safety leash.



2.5b Extraction of the implant from the open side of the holder by means of the hand screwdriver. Take care to exert the extraction parallel to the longitudinal plan of the holder. A force applied in a different direction could cause difficulty in removing the carrier from the package and a possible contact with the surface of the implant.

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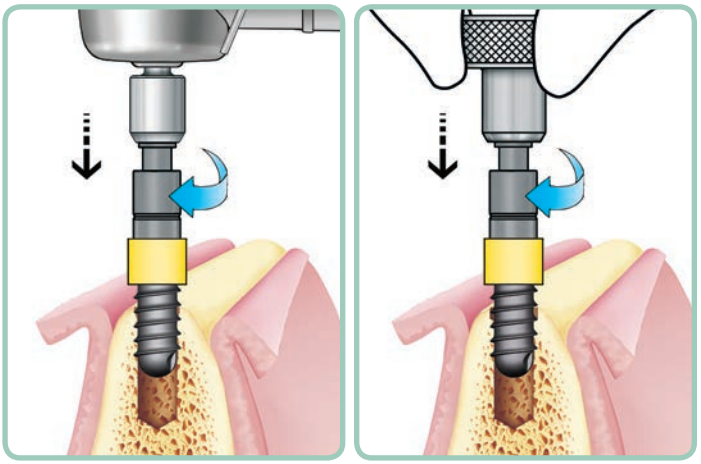
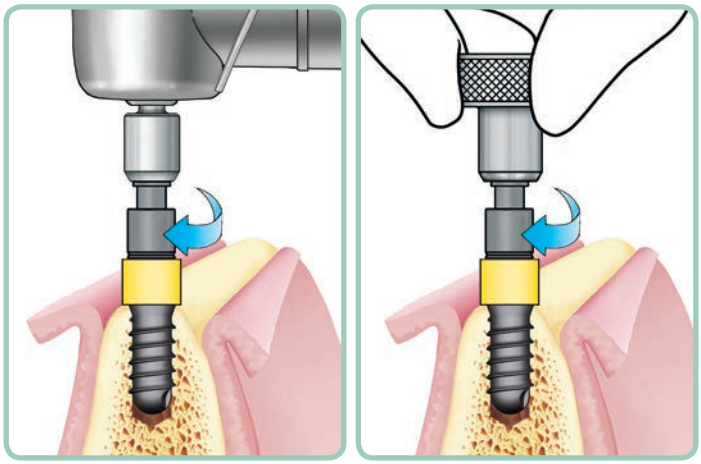
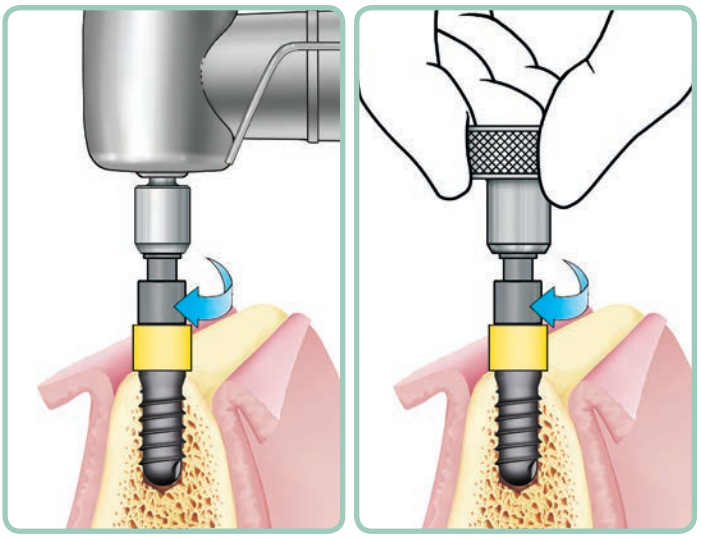


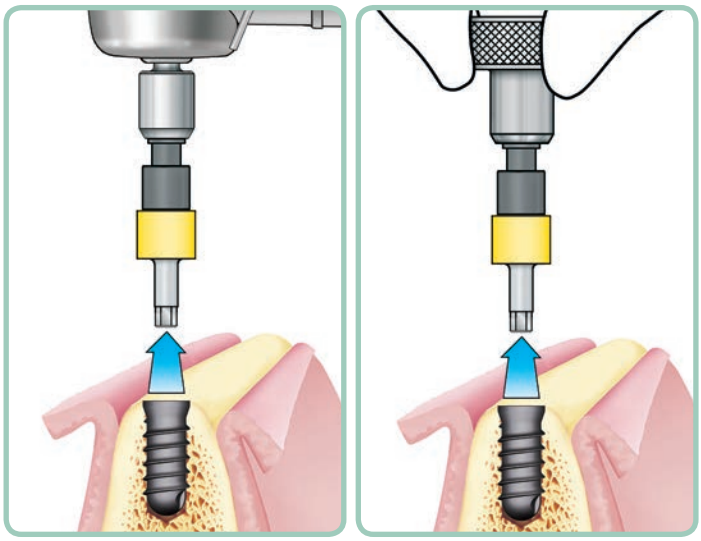
2.6 Initial seating of the implant into the implant site without irrigation.
In case of using a handpiece, set a micromotor's maximum speed to 20 rpm and a maximum torque value to 50 Ncm.
If there is not enough space for a direct connection between the carrier and the handpiece adapter or the hand screwdriver, the extension Cat. 156-1002-00 may be used.



2.7 While driving the implant into the implant site, the rubber ring slides up along the carrier.



2.8 When the carrier's rubber ring has reached the reference line, the implant is exactly positioned at the level of the alveolar crest. Now the carrier can be easily disconnected from the implant.



2.9 Removal of the carrier from the implant.

2.10 Rinsing and drying of the implant's inner side before placing the cap.

At this stage, either a "Two-stage surgical procedure" or a "One-stage surgical procedure" may be followed.

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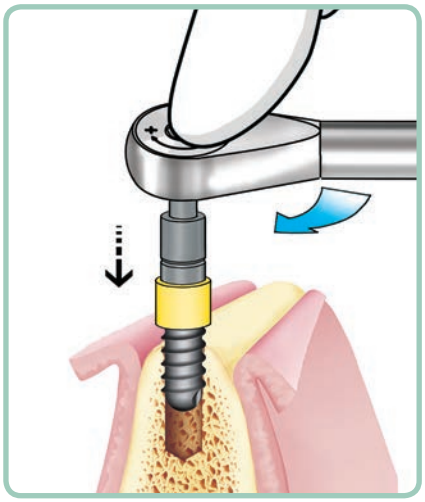
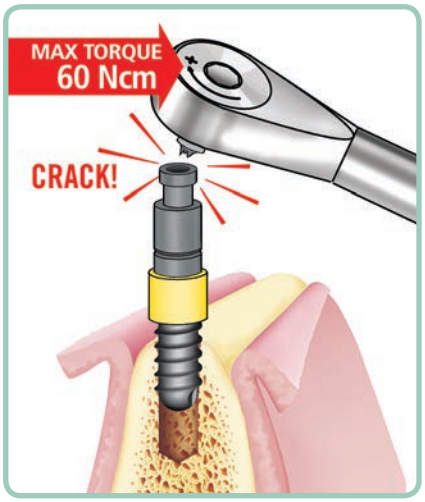
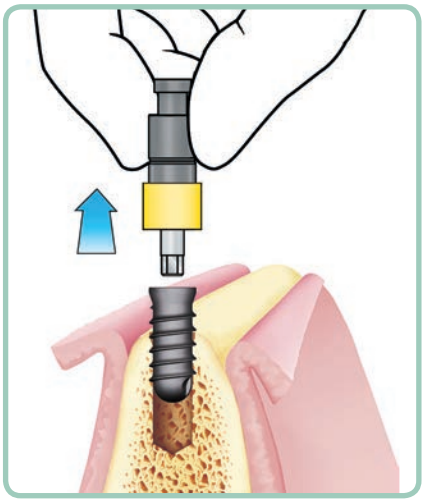


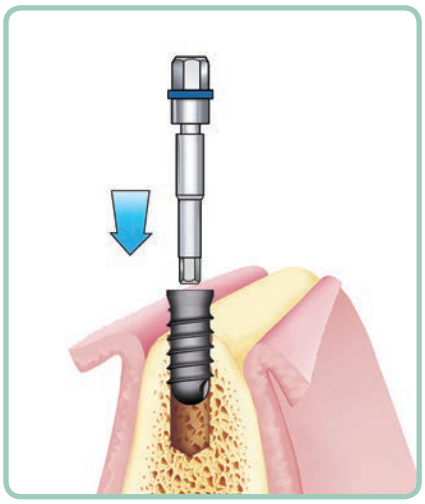
2.11 Should a ratchet be utilized, the forces exerted on the implant and on the correspondent periimplant bone can become excessive.



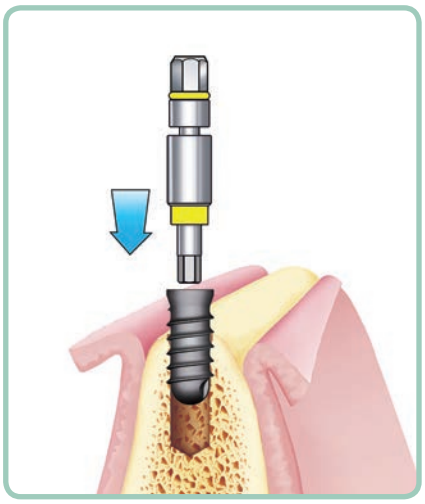
2.12 In this eventuality, should a value of 60 Ncm be overcome, a torque limiting device makes the carrier break above the connection with the implant; now the carrier can be removed.
Note that carrier fracture is not always visible, but it is detectable by a sudden loss of functionality of the insertion instrument accompanied by a sharp crack.



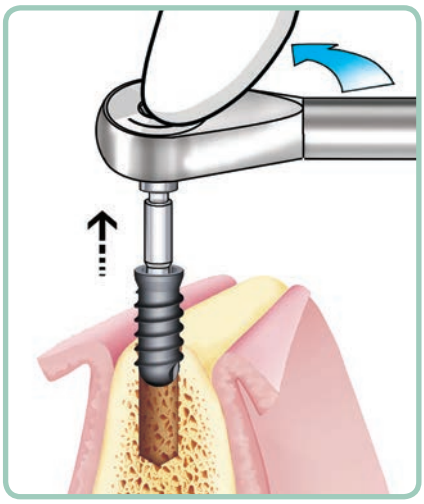
2.13 Removal of the fractured carrier.



2.14a Replace the carrier with the driver for implant (Cat. 156-1013-00 available either in the surgical kit or in the organizer for instruments) withstanding up to a torque applied of 140 Ncm and allowing the removal of the implant.



2.14b It is possible to use special drivers specific for each connection size, which are more stable thanks to the conical support ring and thus more resistant to the application of bending forces.



2.15 Removal of the implant from the implant site.
Tapping and reinsertion of the implant.

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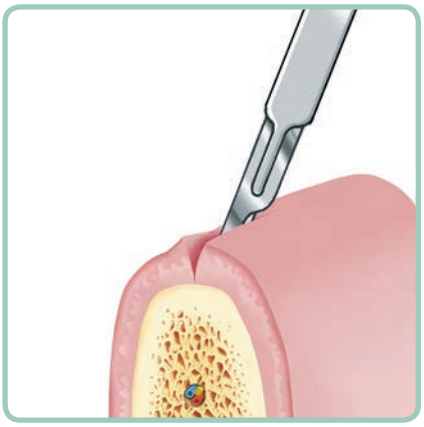
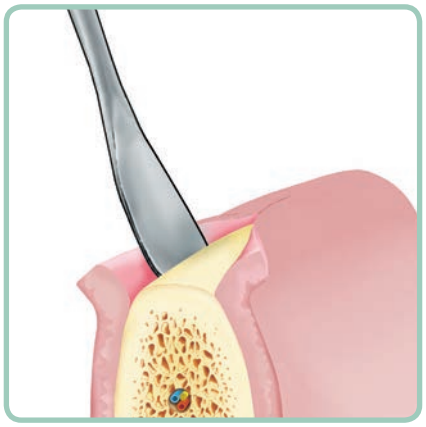
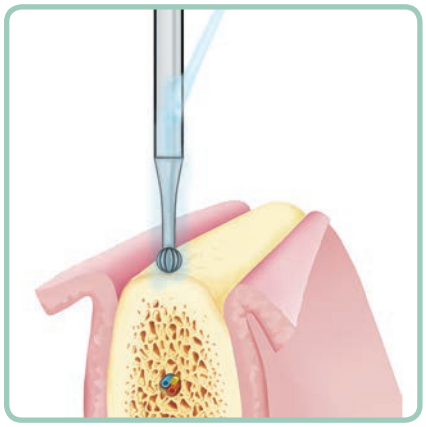
3) LEONE 6.5 SHORT IMPLANT: PREPARATION OF THE IMPLANT SITE

The **LEONE 6.5** short implant is intended for use in cases with limited vertical bone availability. The typology and the access to the surgical site shall be selected by the professional according to the clinical-morphological parameters. Schematically and with illustrative purpose only, the following steps for the preparation of the implant site are illustrated.

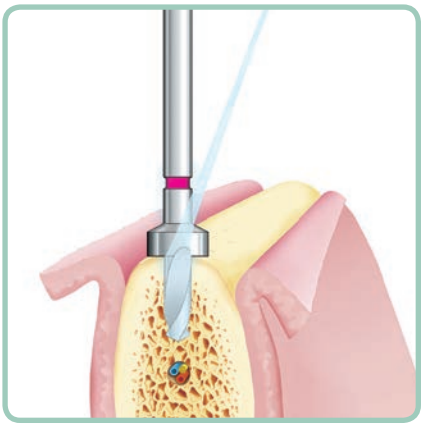




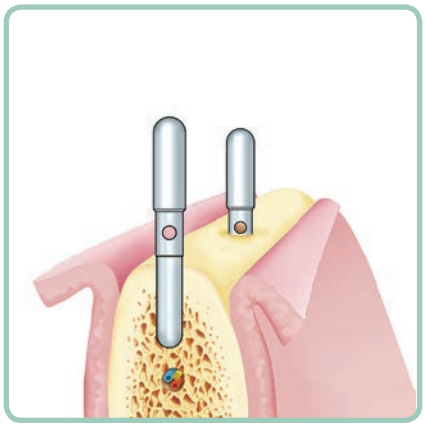
3.1 Full-thickness incision of the soft tissues and detachment of the gingival flaps to have access to the bone ridge.



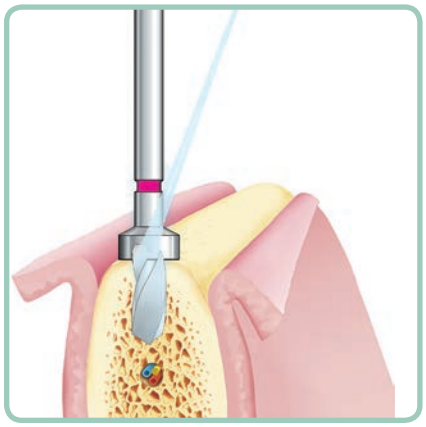
3.2 Use of the round bur Cat. 151-1934-01 to mark the cortical bone for the subsequent drills. Alternatively, it is possible to use the lance drill Cat. 151-1930-02, which is particularly suitable in case of narrow knife-edged ridges.



3.3 Use of the Ø 2,2 mm pilot drill with integrated stop, Cat. 151-2233-65: insert the drill up to the stop. (Max speed: 800 rpm with adequate irrigation).



3.4 Use of paralleling pins as an aid for proper alignment with natural teeth and/or other adjacent implant sites. A radiographic exam can be performed to increase accuracy in the evaluation of parallelism. The paralleling pin can also be utilized after the application of a Ø 2.8 mm twist drill with integrated stop, Cat. 151-2833-65, taking care to seat the pin in the implant site from the side with the larger diameter. Paralleling pins present a hole for the placement of a safety leash.



3.5 Use of the Ø 2,8 mm twist drill with integrated stop, Cat. 151-2833-65: insert the drill up to the stop. (Max speed: 600 rpm with adequate irrigation).

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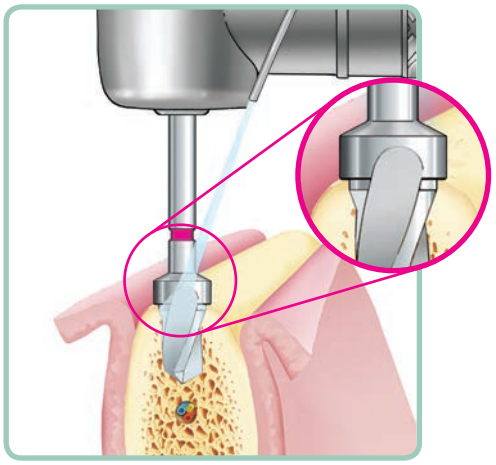
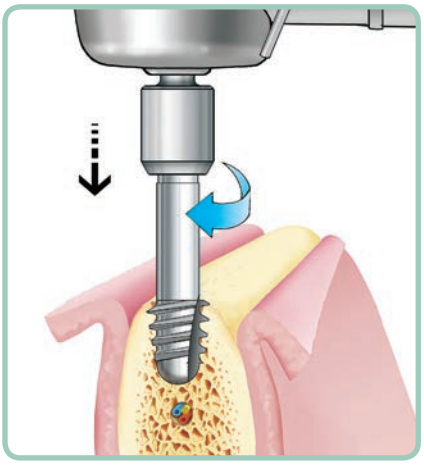
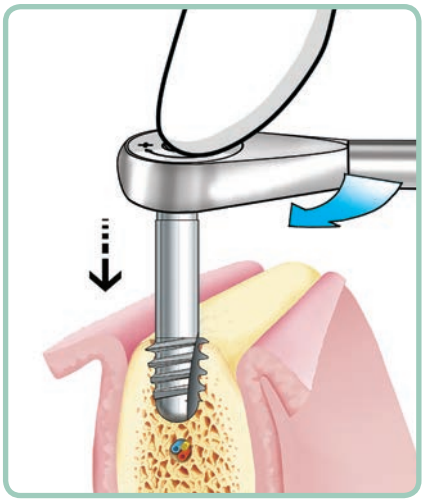


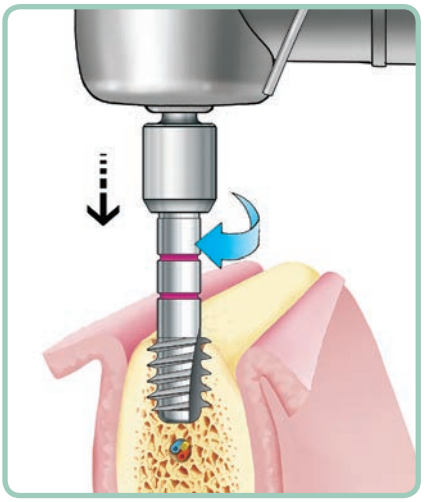
3.6 Use of the Ø 3.5 mm twist drill with integrated stop and crestal countersink, Cat. 151-3533-65: insert the drill up to the stop, (Max speed 500 rpm with adequate irrigation).
The drill's geometry allows also the shaping of the conical region of the implant bed.



3.7a Use of the bone tap "A" Cat. 152-5021-01 in combination with the specific handpiece adapter Cat.156-1002-01: attach the tap to the handpiece, then tap the implant site until the tap's threaded portion is totally inside the bone; the use of the handpiece ensures the maintenance of the implant site axis.
Set a micromotor's maximum speed of 30 rpm and a maximum torque value of 50 Ncm.



3.7b If the maximum torque value of 50 Ncm is not enough to complete the tapping operation, remove the handpiece adapter from the bone tap and attach the ratchet Cat.156-1014-00. Complete the tapping operation until the tap's threaded portion is totally inside the bone.
If the space for a direct connection between the bone tap and the instruments is not enough, the extension Cat. 156-1002-00 may be used.



3.8 In case of high bone density, the bone tap "B" Cat. 152-5021-02 has to be necessarily used **after tapping with bone tap "A":** steps 3.7a and 3.7b. shall be repeated.
The bone tap "B" can easily be distinguished from bone tap "A" by two fuchsia-coded marks on the instrument.

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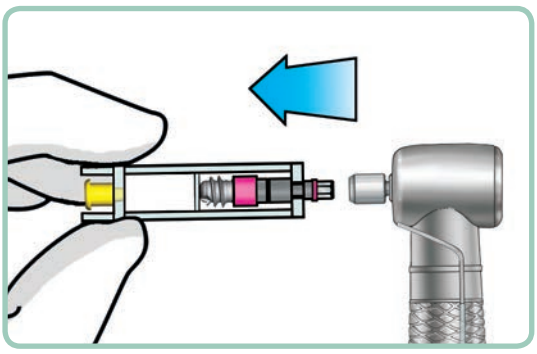
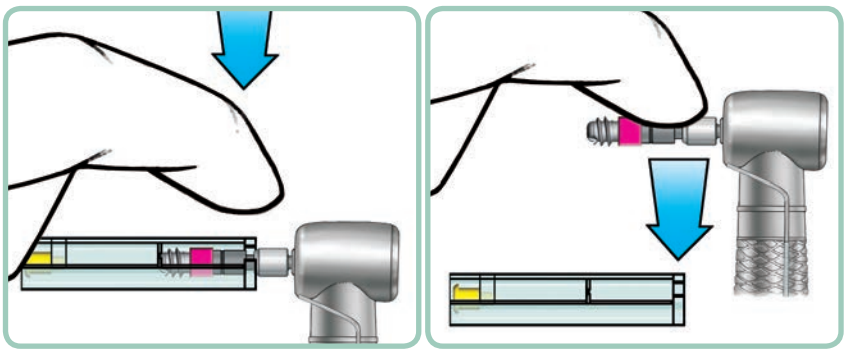
4) LEONE 6.5 SHORT IMPLANT: PLACEMENT OF THE IMPLANT

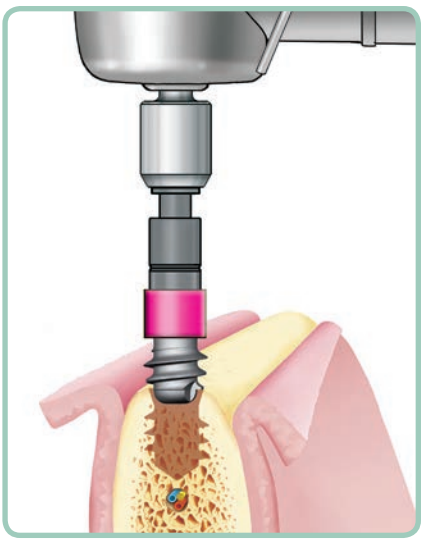
For the extraction of the implant holder from the **LEONE 6.5** short implant package, follow the instructions illustrated at points 2.1-2.2-2.3:



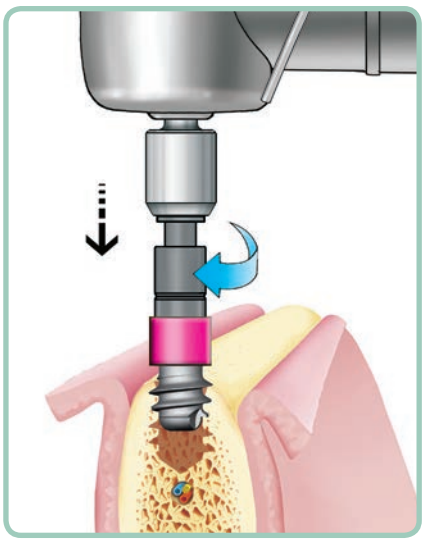
4.1 Connection of the handpiece adapter to the carrier of the implant; the use of the handpiece ensures the maintenance of the implant site axis.



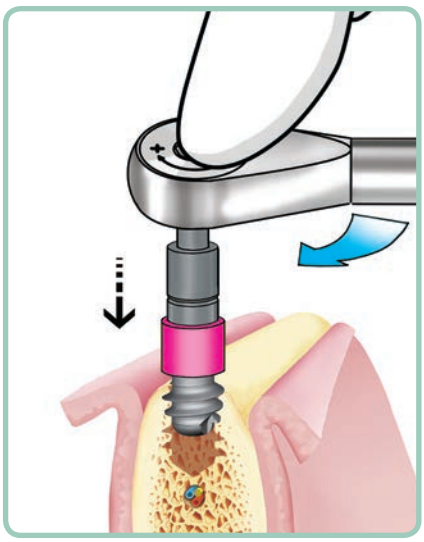
4.2 Extraction of the implant from the holder by exerting a pressure on the open side in order to detach the implant and make the holder fall down.



4.3 Initial seating of the implant in the implant site. If there is not enough space for a direct connection between the carrier and the handpiece adapter, the extension Cat. 156-1002-00 may be used.



4.4 Seating of the implant with a micromotor for implants. Set a micromotor's maximum speed of 20 rpm and a maximum torque value of 50 Ncm. Do not irrigate while placing the implant.



4.5 If the maximum torque value of 50 Ncm is not enough to complete the insertion of the implant, remove the handpiece adapter from the carrier and attach the ratchet Cat.156-1014-00. Be sure the instrument is directed in the long axis by gentle pressing the head of the instrument with a finger.

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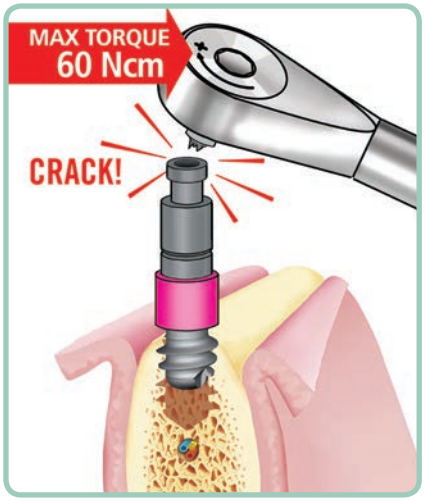
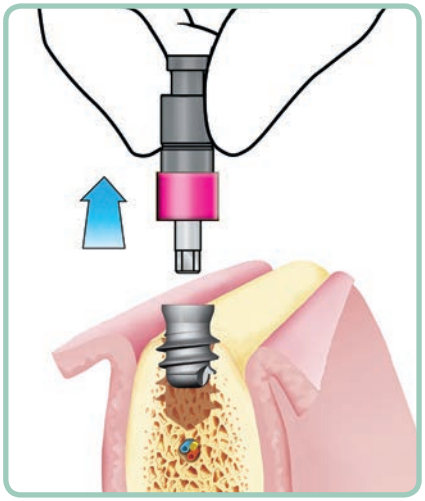
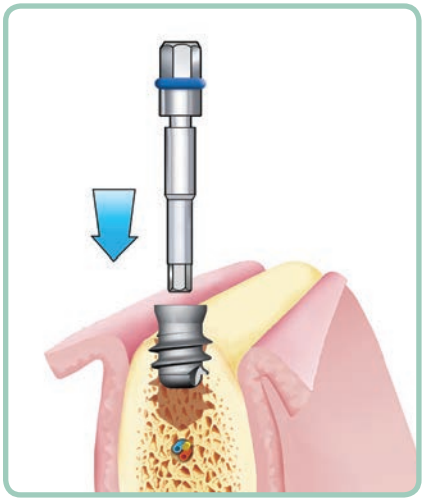


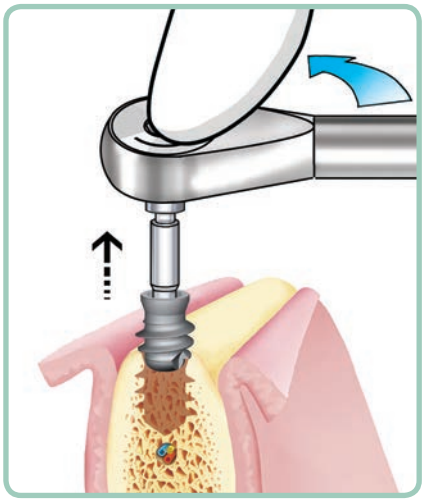
4.6 When using a ratchet, the forces exerted on the implant and on the correspondent periimplant bone can become excessive.
In this eventuality, should the value of 60 Ncm be overcome, a torque limiting device makes the carrier break above the connection with the implant; now the carrier can be removed.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



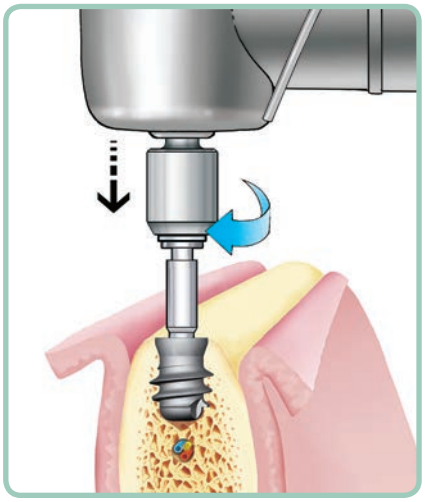
4.7 Removal of the fractured carrier.



4.8 Replace it with the implant driver Cat. 156-1013-00 available either in the surgical kit or in the organizer Cat. 156-0019-00. It withstands a torque value applied up to 140 Ncm and allows the removal of the implant. It is possible to use the implant driver Cat. 156-1041-00, which is more stable thanks to the conical support ring and thus more resistant to the application of bending forces.

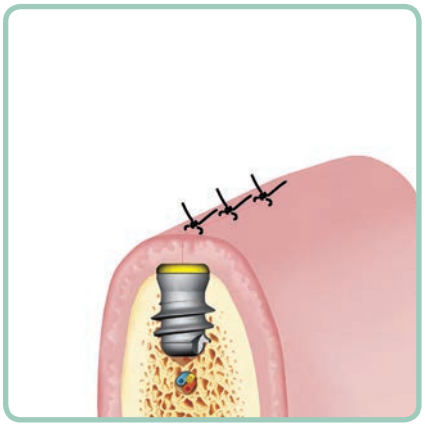


4.9 Attach the ratchet to the driver and remove the implant from the implant site. Tapping of the site with bone tap “B”.



4.10 Place again the implant by means of the implant micromotor with the driver attached to the handpiece adapter. Set a micromotor’s maximum speed of 20 rpm and a maximum torque value of 50 Ncm. If the maximum torque pre-set value is not enough to complete the insertion of the implant, remove the hand piece adapter from the driver and attach the ratchet.

4.11 Rinsing and drying of the implant’s inner side before placing the cover cap.



4.12 In order to complete the placement of the implant, follow the steps for “Two stage surgical procedure” (see point 5 “Two stage surgical procedure: first stage”) and instructions at points 6, 7 or 8 for the conditioning of soft tissues.

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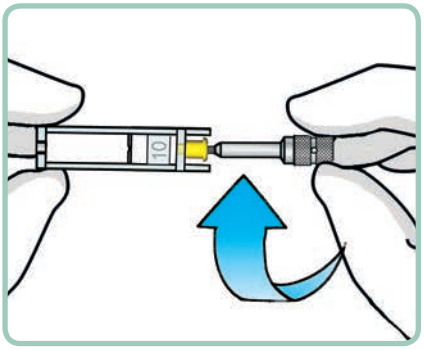
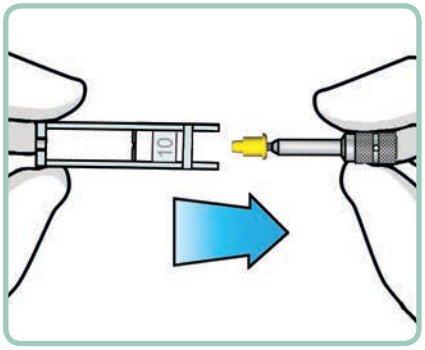
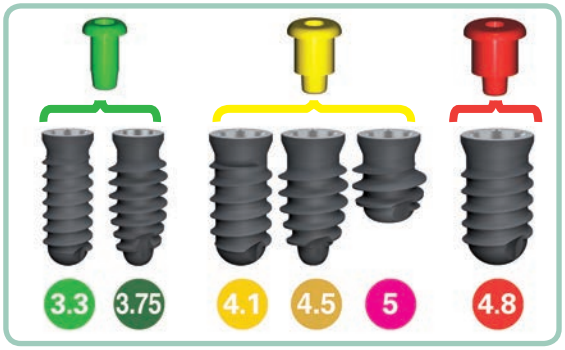
5) TWO-STAGE SURGICAL PROCEDURE: FIRST STAGE

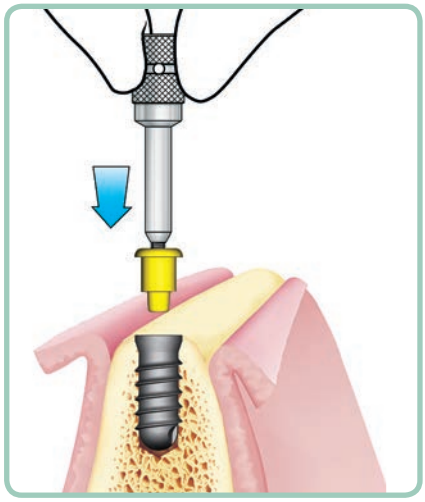




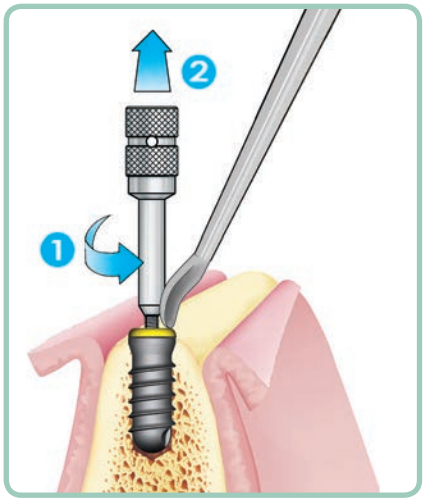
5.1 Take the holder that previously contained the implant. Screw the instrument for cover caps, Cat. 156-1003-00, onto the head of the cover cap. Do not screw the instrument all the way in, but only half way the length of the threaded part. The instrument for cover cap presents a hole for the insertion of a safety leash. Removal of the biopolymer sealing cap from the holder by exerting a gentle extraction.



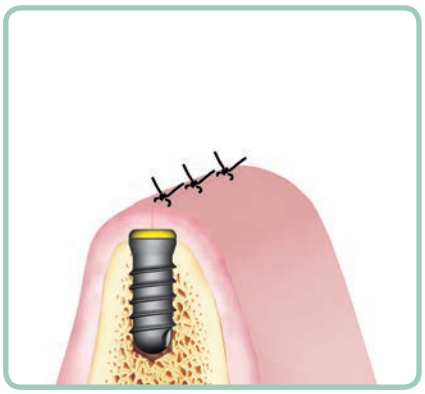
5.2 In case of positioning of several implants, the colour of the cover cap allows an immediate recognition of the correct connection size for the subsequent prosthesis component.



5.3 Rinsing and drying of the implant's inner side. Positioning of the cover cap on the implant: push the cap home inside the implant.



5.4 Removal of the instrument for cover cap by unscrewing in an anti-clockwise direction while holding the cover cap in place with an instrument. Push now the cover cap inside to its final position with a non sharp tool to get a perfect sealing of the implant.



5.5 The gingival flaps are sutured for total coverage of the implant.

*The average period for the attainment of a good osseointegration, which is facilitated by the **HRS** surface that covers all **LEONE** implants, is about 3 months. This period may however vary up to 8 months depending on the type of surgical intervention, the quality of the bone and the individual patient response. Clinical check-ups and instrumental exams are absolutely necessary.*

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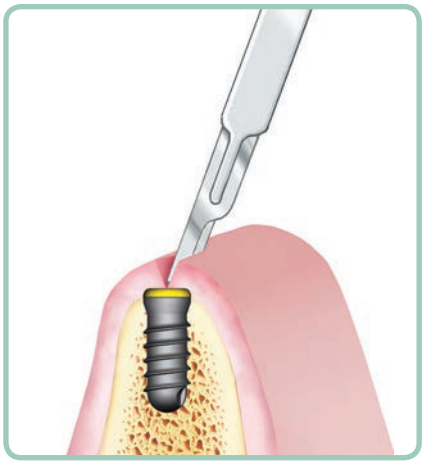
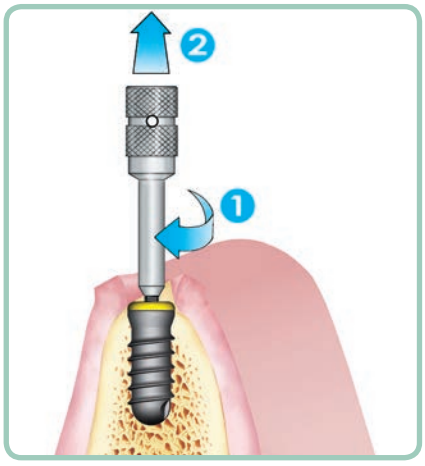
6) TWO-STAGE SURGICAL PROCEDURE: SECOND STAGE



6.1 Once osseointegration has occurred, the position of the implant is identified and an incision of the soft tissue covering the implant is performed.

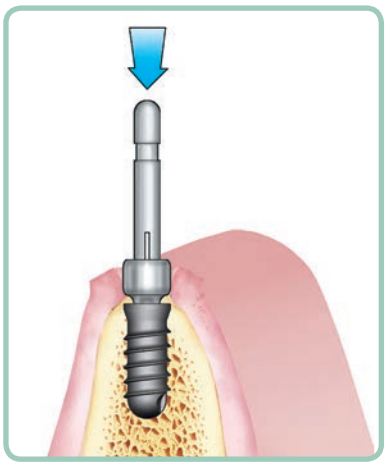


6.2 Removal of the cover cap with the specific instrument Cat. 156-1003-00 that is supplied either in the surgical kit or in the instrument organizer. The instrument for cover cap has to be screwed into the head of the cover cap to be able to practice enough traction to remove the cap.

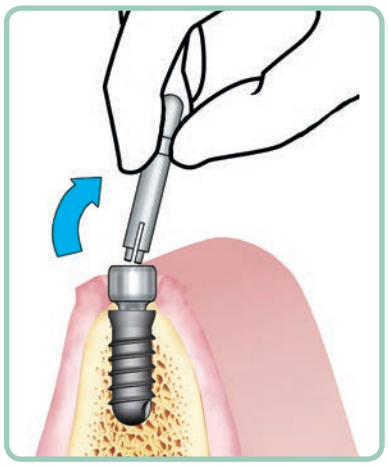
6.3 Accurate rinsing and drying of the implant's inner part.

Follow the steps described at chapters 7 or 8 according to the selected platform.

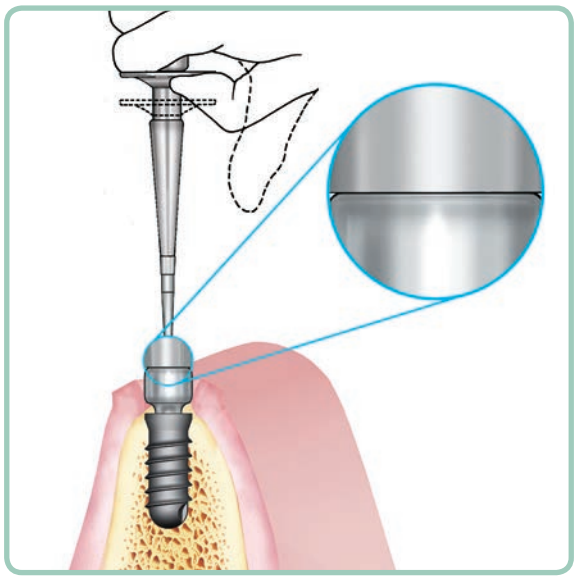
7) TWO-STAGE SURGICAL PROCEDURE: CONDITIONING OF THE SOFT TISSUES FOR STANDARD AND LARGE PLATFORM



7.1 Place the appropriate healing cap (supplied sterile) onto the implant by means of the carrier. Exert a pressure on the carrier.



7.2 Removal of the carrier with a gentle side bending and pull.



7.3 Percussion on the healing cap by means of the specific beater (page 38) to activate the locking-taper connection. One percussion is advisable.

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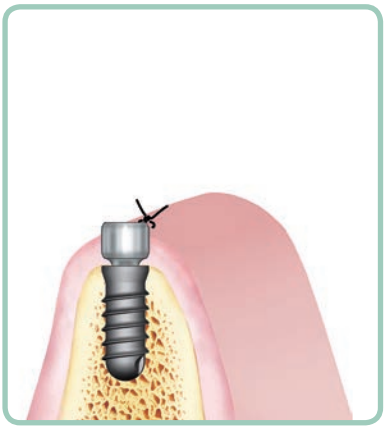
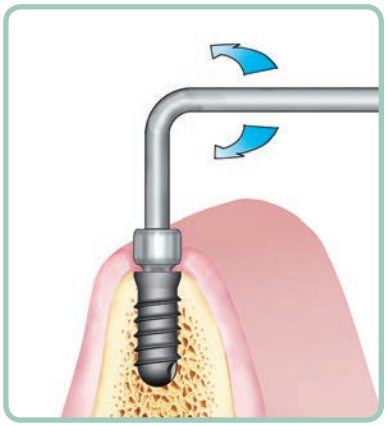


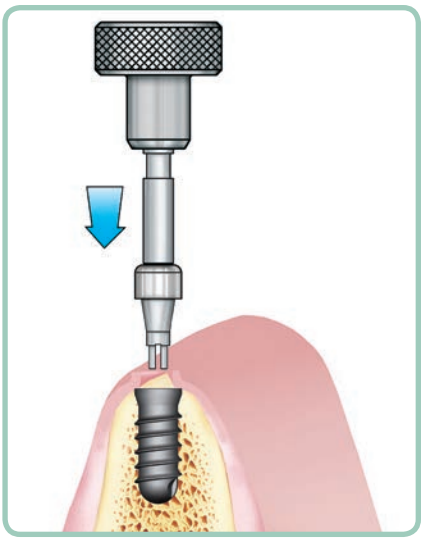
7.4 Suture of the soft tissues around the healing cap.



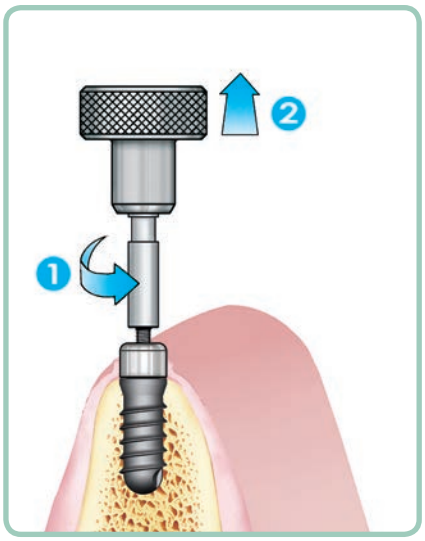
7.5 When the healing process has occurred, the healing cap is unlocked by means of the specific hex-head extractor, Cat. 156-1006-00. The extractor, with a hole for the placement of a safety leash, is seated into the hexagon on the head of the healing cap and rotated subsequently, either clockwise or anti-clockwise, in order to unlock the healing cap. By using tweezers, the cap is removed from the implant. The implant is now ready for the prosthetic phase.

*For the impression taking, the preparation of the abutment and the fabrication of the final prosthesis, refer to the "Prosthetic Procedure of the **LEONE** Implant System".*

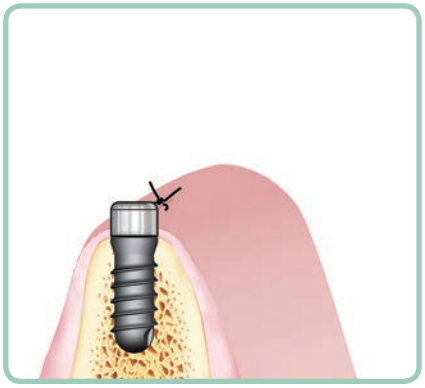
8) TWO-STAGE SURGICAL PROCEDURE: CONDITIONING OF THE SOFT TISSUES FOR SLIM PLATFORM



8.1 Positioning of the healing cap (supplied sterile) on the implant by means of the special carrier eventually connected to a hand screwdriver to facilitate its taking.
When its hexagonal shape is engaged, exert a pressure on the healing cap to get a perfect closure of the implant.



8.2 Removal of the carrier by unscrewing in an anti-clockwise direction.
The operation can be facilitated by connecting the carrier to a hand screwdriver.



8.3 The soft tissues are sutured around the healing cap.

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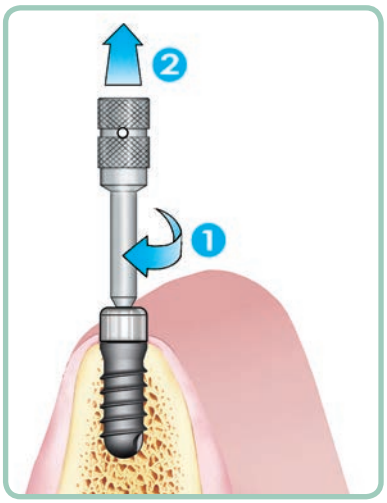
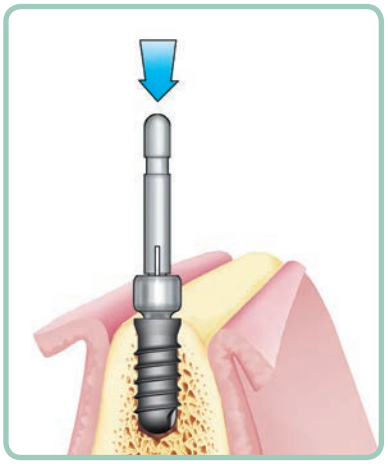


8.4 When the healing process has occurred, the healing cap is removed by means of the instrument for cover cap Cat. 156-1003-00 which is provided in the surgical kit or in the organizer for instruments. The instrument for cover cap has to be screwed into the head of the healing cap to be able to practice enough traction to remove the cap.

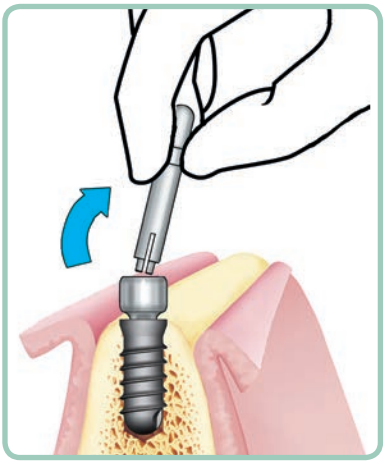
*For the impression taking, the preparation of the abutment and the fabrication of the final prosthesis, refer to the "Prosthetic Procedure of the **LEONE** Implant System".*

9) ONE-STAGE SURGICAL PROCEDURE FOR STANDARD AND LARGE PLATFORM

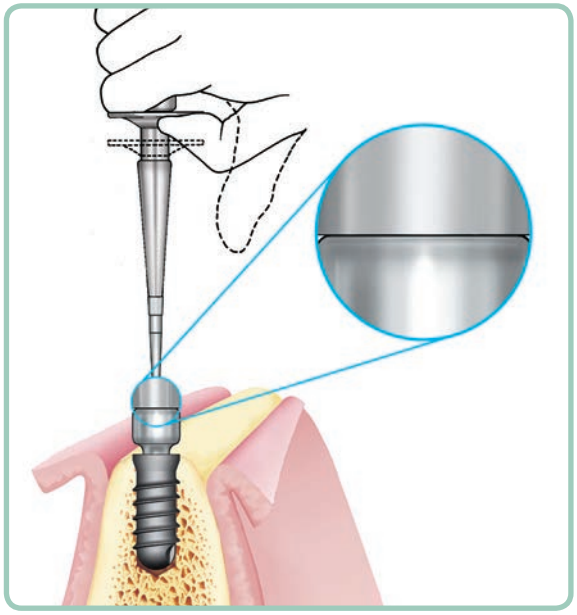
For previous steps refer to chapters 1) and 2).



9.1 Rinsing and drying of the implant's inner side.
Sealing of the implant with the healing cap (supplied sterile) by means of the carrier. Exert a pressure on the carrier.
In case of flapless procedure and subcrestal implant placement, do not use Large healing caps.



9.2 Removal of the carrier with a gentle side bending and pull.



9.3 Percussion on the healing cap by means of the specific beater to activate the locking-taper connection. One percussion is advisable.

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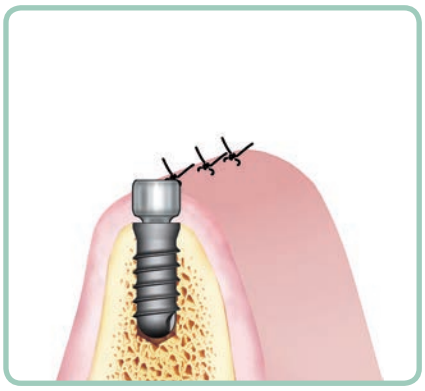
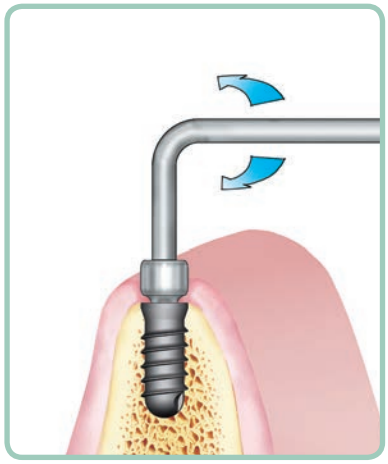


9.4 Suture of the soft tissues around the healing cap.

*The average period for the attainment of a good osseointegration, which is facilitated by the HRS surface that covers all **LEONE** implants, is about 3 months. This period may however vary up to 8 months depending on the type of surgical intervention, the quality of the bone and the individual patient response. Clinical check-ups and instrumental exams are absolutely necessary.*



9.5 When osseointegration has occurred unlock the healing cap by means of the specific hex head extractor Cat. 156-1006-00. The extractor is seated into the hexagon which is present on the head of the healing cap and rotated either clockwise or anti-clockwise, in order to unlock the healing cap. The extractor presents a hole for the placement of a safety leash. The cap is removed from the implant with the use of tweezers. The implant is now ready for the prosthetic procedure.

*For the impression taking, the preparation of the abutment and the fabrication of the final prosthesis, refer to the "Prosthetic Procedure of the **LEONE** Implant System"*

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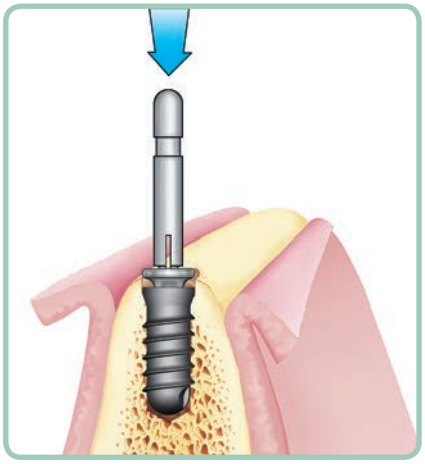
10) LOW SELF-LOCKING CAPS: INSTRUCTIONS FOR USE AND PROCEDURE

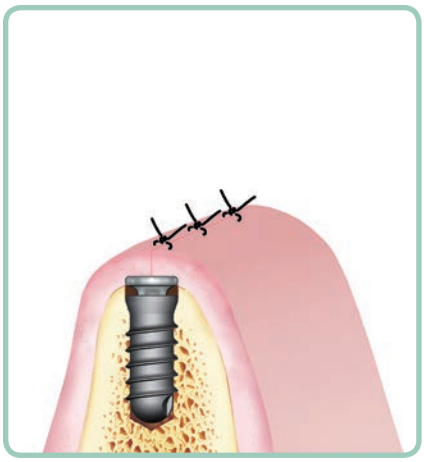
Premise
The low self-locking caps shall be used:
a) during the two-stage (see point 5) surgical technique in place of the cover caps in case of post-extraction or subcrestal positioning of the implant
b) during either the two-stage (see point 7) or one-stage (see point 9) surgical technique in place of the healing caps in case of low gingival thickness.

a) USE IN PLACE OF COVER CAPS

10.1a First surgical stage: the implant is seated below the alveolar crest level.

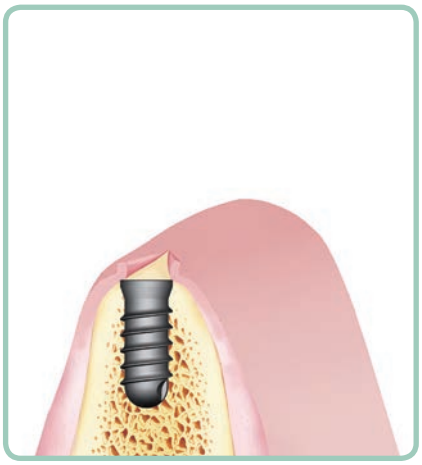


10.2a Positioning of the low self-locking cap (supplied sterile) on the implant with the carrier. Follow steps 7.2 and 7.3 to activate the locking-taper connection.

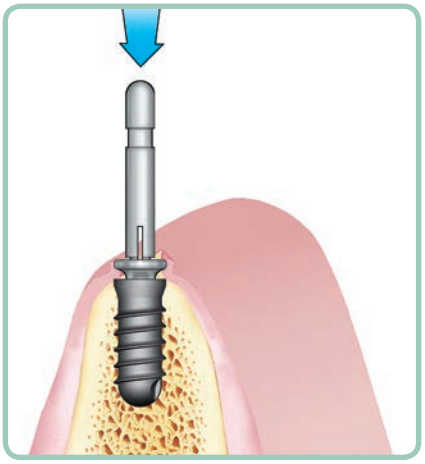


10.3a The gingival flaps are sutured for total coverage of the implant.
When osseointegration has occurred, after flap re-opening follow steps 10.4b and 10.5b.

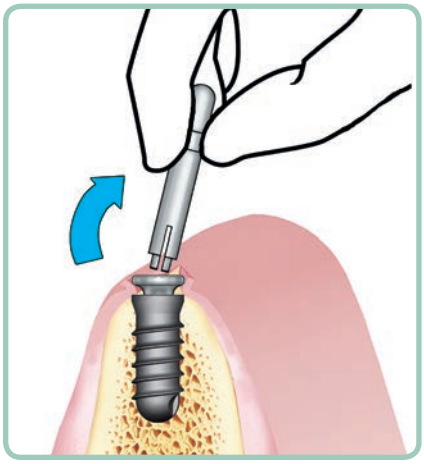
b) USE IN PLACE OF HEALING CAPS



10.1b The implant is at the alveolar crest level. Rinsing and drying of the implant's inner side.



10.2b Positioning of the low self-locking cap (supplied sterile) on the implant with the carrier.



10.3b Removal of the carrier with a gentle side bending and pull. Follow steps 7.3 and 7.4 to activate the locking-taper connection and to suture the soft tissues.

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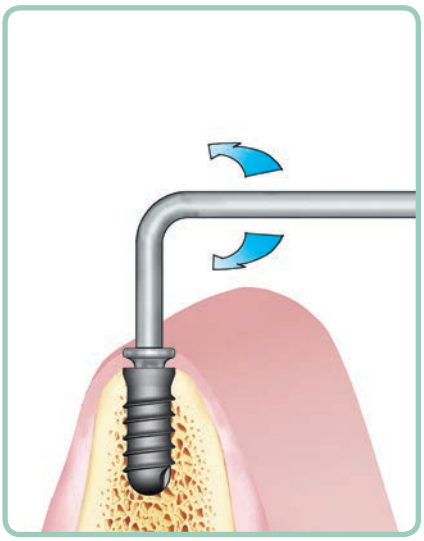
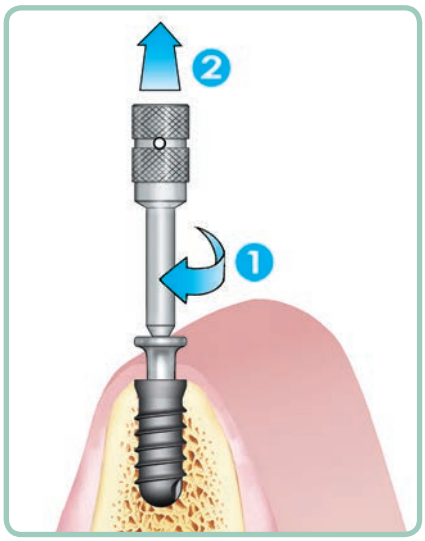


10.4b When osseointegration and healing of the soft tissues have occurred, unlock the low self-locking cap by means of the specific hex head extractor Cat. 156-1006-00. The extractor is seated into the hexagon which is present on the head of the cap and rotated either into a clockwise or anti-clockwise direction.



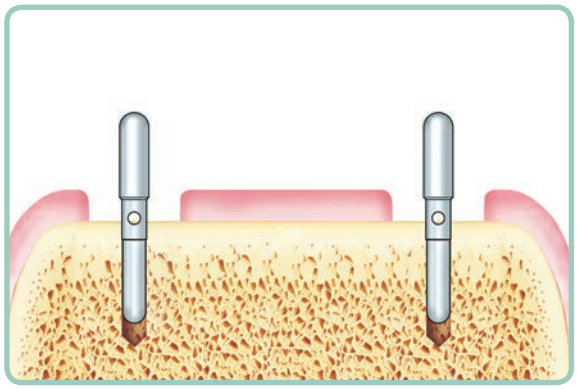
10.5b Screw the instrument for cover caps, Cat. 156-1003-00, onto the head of the low self-locking cap. Remove the cap with a gentle pull. Now the implant is ready for the prosthetic stage.

*For the impression taking, the preparation of the abutment and the fabrication of the final prosthesis, refer to the "Prosthetic Procedure of the **LEONE** Implant System".*

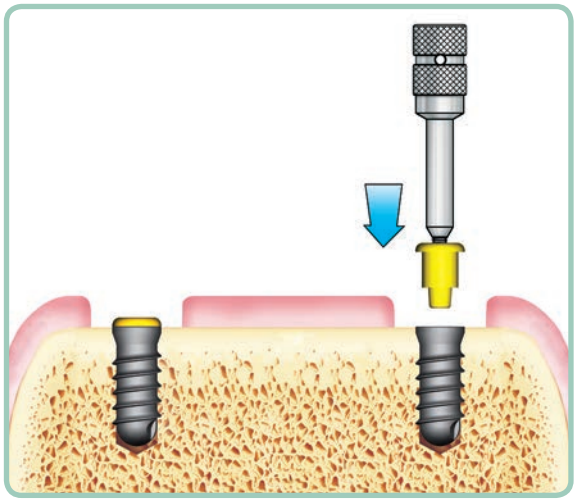
11) OVERDENTURE: TWO-STAGE SURGICAL PROCEDURE FOR STANDARD PLATFORM

Premise
Abutments for attachment-retained overdenture (O-ring or insert) and for bar-retained overdenture are available. In order to manufacture an overdenture, a perfect parallelism among the implants is necessary. To support an overdenture in the lower jaw a minimum of 2 implants is required and in the upper jaw a minimum of 4 implants. The two-stage surgical procedure, as described at steps 5), 6) and 7), is recommended.
It is possible to fabricate an overdenture with a new or a pre-existing prosthesis, the second case must be evaluated by the clinician.

The herewith graphical illustrations refer to the placement of two implants in the mandible.



11.1 Preparation of the implant sites, with a special care for parallelism.



11.2 Placement of the implants and cover caps.

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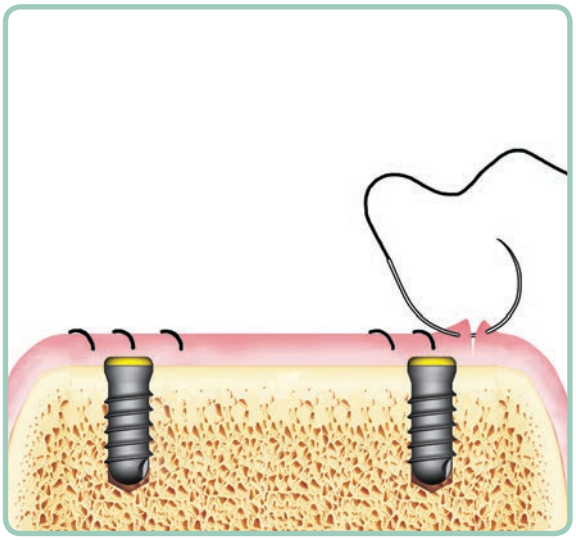
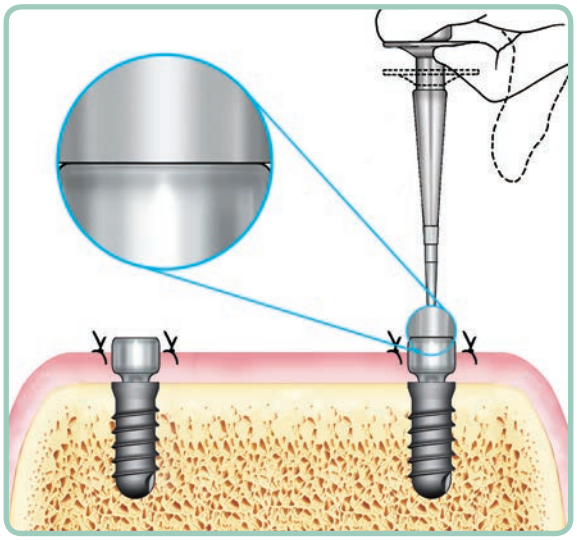
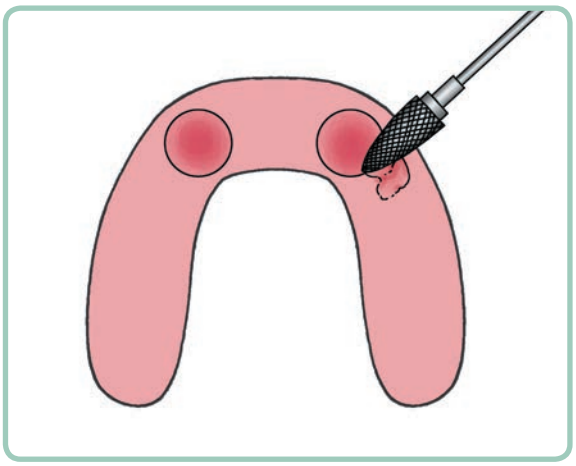


11.3 The gingival flaps are sutured for total coverage of the implants. It is recommended to wait several days before using a temporary prosthesis or the pre-existing prosthesis of the patient. The resin of the prosthesis, however, must be removed in the area of the implants and rebased with soft resin.



11.4 After the attainment of a good osseointegration of the implants, the implants are exposed and the cover caps are removed.

11.5 Placement of the Standard healing caps for the conditioning of the soft tissues. One percussion is advisable.



11.6 Adjustment of the temporary or pre-existing prosthesis with removal of the acrylic in the areas corresponding to the healing caps.

11.7 After the healing of the soft tissues, the final overdenture is fabricated.

*For the fabrication of the final prosthesis, refer to the "Prosthetic Procedure of the **LEONE** Implant System".*

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LEONE MAX STABILITY IMPLANT SURGICAL PROCEDURE

Please consult *Disclaimer*, *Treatment planning and preoperative exams* (page 52).

MAX STABILITY IMPLANT SELECTION

Max Stability implants are indicated for use in cases of poor bone density or when performing immediate implant placement.
Do NOT use Max Stability Implants in thick cortical bone, equivalent to D1 bone density according to the Misch Classification.[1]

The number and dimensions (diameter and length) of the implants to be seated 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.

A template, Cat 156-2003-04, is available showing **Max Stability** implants in actual dimensions, with dimensions increased by 10% and increased by 25%, to match possible distortions created by the instrument for radiographic examinations (CT, panoramic radiograph, standard and digital cephalograms).
Superimpose the template to the radiograph in order to select the implant in relation to the quantity of bone available.

Do not *insert a single* ***Max Stability*** *Ø3.75 mm implant in the molar position.*

The ***Max Stability*** *Ø3.75 mm implant, 8 mm in length, must be used as a supplementary implant in the prosthesis composed of two or more implants of any diameter and length.*

Do not place the implants above the level of the alveolar crest.

The **LEONE** implant system is characterized by a high mechanical resistance validated through fatigue strength testing according to the ISO 14801 international standard, which indicates to perform testing with a cyclic loading at an angle of 30° with respect to the implant-abutment axis. For the **LEONE** implants of minor diameter, and thus the most relevant ones, the results are: Ø3,3 mm and Ø3,75 mm implant fatigue strength: 240 N; Ø4,1 mm, Ø4,5 mm and **LEONE 6.5** short implant fatigue strength: 392 N.[2,3]
In the literature, in comparison, it is reported that the average force generated during mastication is 145 N with inclinations up to 10°.[4,5] It should also be underlined that very high masticatory forces[6] 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.

ORGANIZER FOR LEONE MAX STABILITY IMPLANTS

Organizers are available for sterilizing and clearly arranging all the instruments necessary for the planned surgical intervention.
The organizer is fully autoclavable and can hold up to 8 instruments using a colour coded positioning system.
The organizer must be wrapped and sterilized before every use.
The sterilization must be done as follows:

- wrap the organizer into a sterilization bag as requested by the manufacturer of the sterilizing machine;
- autoclave at 121° (250°F) for 20 minutes;
- remove the organizer from the autoclave and leave it cool inside the bag;
- leave the organizer inside the bag to preserve sterility.

[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
[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] Carlsson GE, Haraldson T. Functional response. In: Branemark P-1. Zarb GA, Albrektsson T. Eds. Tissue integrated prostheses. Osseointegration in clinical dentistry. Chicago: Quintessence, 1985:155-63
[5] 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
[6] Craig RG. Restorative dental material. 6th ed. St. Louis, C.V. Mosby, 1980

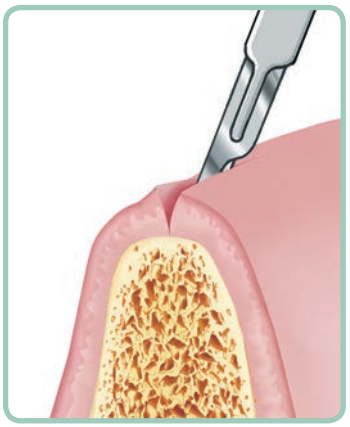
(Proc. 05/10-12 *May 01, 2015*

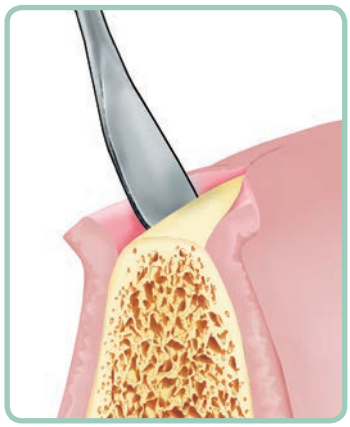
1) LEONE MAX STABILITY IMPLANTS Ø3,75 - 4,5: PREPARATION OF THE IMPLANT SITE

Max Stability implants feature an innovative design developed to increase primary stability in cases where the implant site does not offer adequate initial stability. In particular, these implants are indicated for application in cases of poor bone density or placement in fresh extraction sockets.
In the case of immediate implant placement, subcrestal placement is suggested. The planned level of implant placement should be taken into account when calculating the drilling depth.
In cases of very poor bone density, it is possible to substitute the standard drilling procedure with a bone condensing procedure, using the appropriate bone condenser tips.

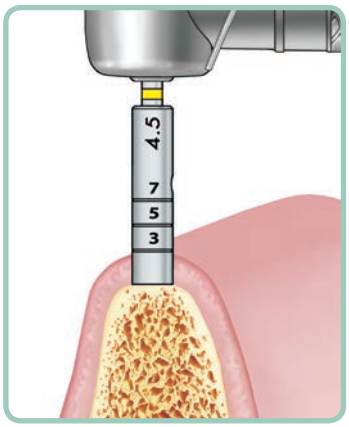
CAUTION: ***do NOT use Max Stability Implants in thick cortical bone, equivalent to D1 bone density according to the Misch Classification.***[1]

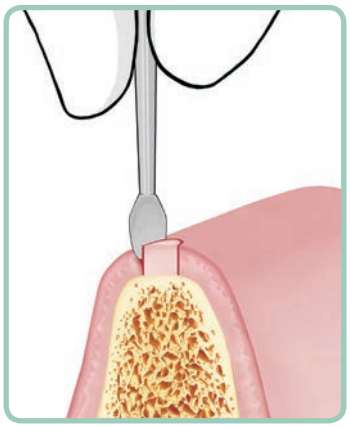
The typology and the access to the surgical site shall be selected by the professional according to the clinical-morphological parameters. Schematically and with illustrative purpose only, the following steps for the preparation of the implant site are illustrated.





1.1a Make full-thickness incision of the soft tissues and detachment of the gingival flaps to have access to the bone ridge.





1.1b If flapless procedure is followed, use the proper mucosa punch for contra-angle. Set the handpiece to low speed (approx. 40 rpm). Use until bony tissue is met. To determine the gingival thickness around the implant area, the three black lines clearly visible around the mucosa punch, at the heights of 3-5-7 mm, starting from the crest bone, may be used.
For Ø3.75 mm implants: use mucosa punch for Ø3.75 mm implants Cat. 154-3815-20.
For Ø4.5 mm implants: use mucosa punch for Ø4.5 mm implants Cat. 154-4515-20.
Remove the tissue plug by using a small periosteal elevator.

[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

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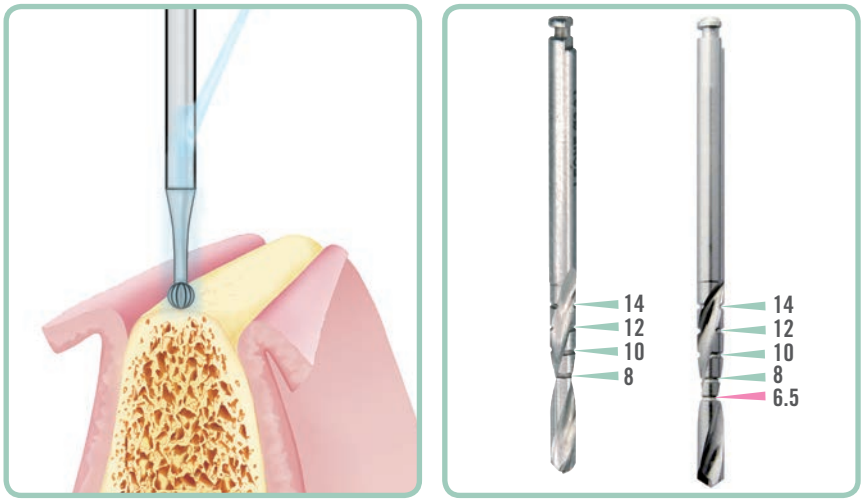
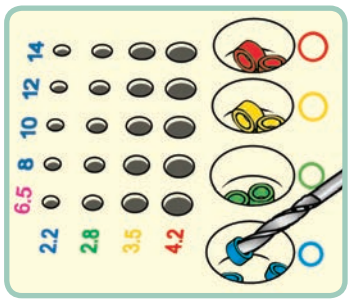


1.2 Use of the round bur Cat. 151-1934-01 to mark the cortical bone for the subsequent drills. Alternatively, it is possible to use the lance drill Cat. 151-1930-02, which is particularly suitable in case of narrow knife-edged ridges.

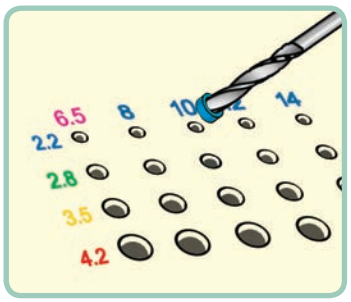
1.3 Prior to using any pilot or twist drill, it is important to check the number of the marks on the body of each drill:
- drills with 4 marks: 8 – 10 – 12 – 14 mm
- drills with 5 marks: 6.5 – 8 - 10 – 12 – 14 mm

The use of the depth indicators is recommended to better visualize the drilling depth.
The depth indicators are made of elastomer, for single use, manufactured in the colour code corresponding with implant diameter.
The depth indicators and the special positioner, available either in the surgical kit or single supplied (Cat. 151-0001-00 page 30), must be sterilized in the autoclave before use.

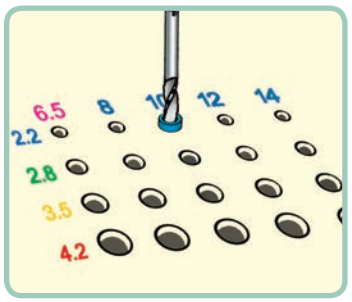
Choose the elastomer ringlet matching the diameter of the drill to be used (Ø2.2 mm pilot drill, blue colour; Ø2.8 mm twist drill, green colour; Ø3.5 mm twist drill, yellow colour; Ø4,2 mm twist drill, red colour).



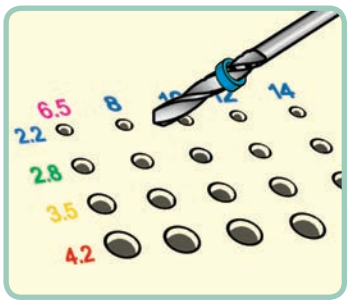
1.4 Seat the ringlet on the tip of the drill.



1.5 Placement of the drill into the hole corresponding to the diameter of the instrument and the selected depth.



1.6 Push the drill all the way to the stop.



1.7 In this way the depth indicator will be driven into position with the corresponding mark for the selected depth.

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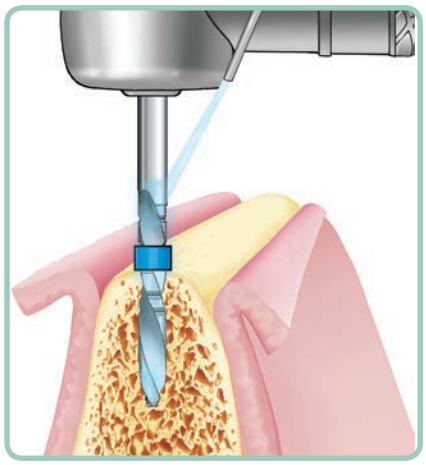
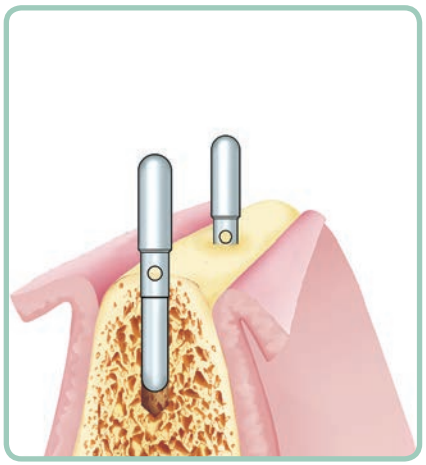
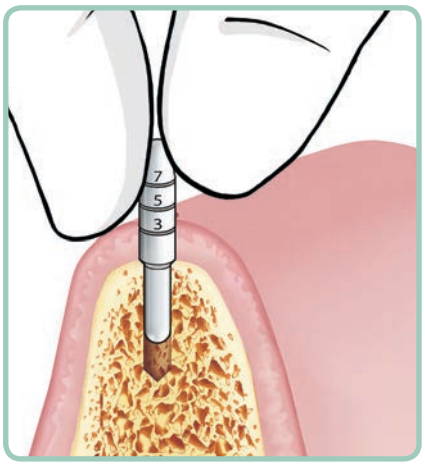


1.8 Use of the Ø2.2 mm pilot drill: drill up to the depth mark **corresponding to the length of the selected implant** (max speed: 800 rpm with adequate irrigation).
In the case of subcrestal positioning, the planned level of implant placement should be taken into account when calculating the drilling depth.

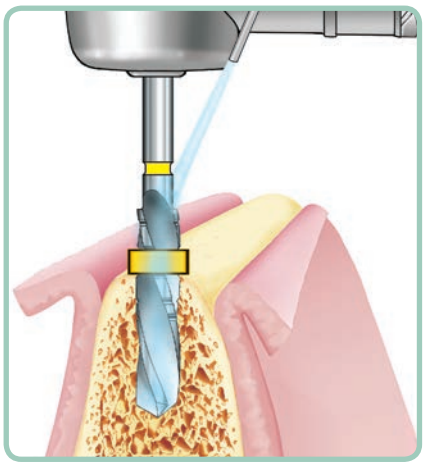


1.9a Use of paralleling pins for the control of parallelism with natural teeth and/or other adjacent implant sites. A radiographic exam can be performed to increase accuracy in the evaluation of parallelism. The paralleling pin can also be utilized after the application of a Ø2.8 mm twist drill, taking care to seat the pin in the implant site using the side with larger diameter. Paralleling pins present a hole for the placement of a safety leash.



1.9b With flapless procedure, use a gingival height measuring pin to check the mucosa height and parallelism with natural teeth and/or other adjacent implant sites.
Gingival height measuring pins present a hole for the placement of a safety leash.

1.10 Use of the depth gauge to check the depth of the newly-created implant site.
The depth gauge presents a hole for the placement of a safety leash.



1.11 Widening of the diameter of the implant site with the progressive use of drills with increasing diameter. The drills have to be used up to the depth mark which **corresponds with the length of the selected implant**:
for Ø3.75 mm implants: use a Ø2.8 mm twist drill (short Cat. 151-2833-13 or long Cat. 151-2841-13) (max speed: 600 rpm)
for Ø4.5 mm implants: after Ø2.8 mm twist drill, use a Ø3,5 mm drill (short Cat. 151-3533-13 or long Cat. 151-3541-13) for the final resizing of the site (max speed: 500 rpm).
Reminder: use adequate irrigation. In the case of subcrestal positioning, the planned level of implant placement should be taken into account when calculating the drilling depth.

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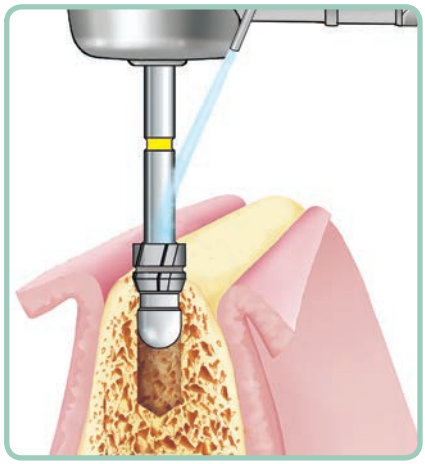

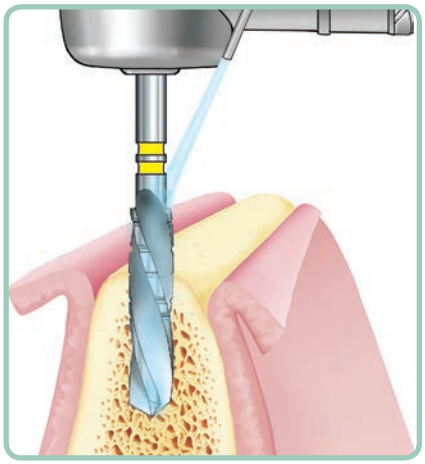

1.12 At the end of the widening operations of the implant site with the twist drills, use the countersink by inserting it up to the reference mark:
for Ø3.75 mm implants: use the Ø3.3 mm countersink drill (Cat. 151-3333-24) (max. speed: 300 rpm with adequate irrigation)
for Ø4.5 mm implants: use the Ø4.1 mm countersink drill (Cat. 151-4133-24) (max. speed: 300 rpm with adequate irrigation).

1.13 In the case of medium-to-high type D2 bone density, it is necessary to use a twist drill with a larger diameter than the one previously used, easily distinguishable by the two colour-coded marks on the drill's stem:
for Ø3.75 mm implants: use a twist drill for hard bone for implant Ø3.75 (short Cat. 151-3133-13 or long Cat. 151-3141-13) (max speed: 500 rpm)
for Ø4.5 mm implants: use a twist drill for hard bone for implant Ø4.5 (short Cat. 151-3833-13 or long Cat. 151-3841-13) (max speed: 400 rpm).
The drill must be used up to the depth mark which **corresponds with the length of the selected implant**.
Reminder: use adequate irrigation.

CAUTION:
In case of placement of a 14mm-long Max Stability implant in mature bone, for the final widening of the implant site always use the proper twist drill for hard bone up to the depth mark of 14 mm.

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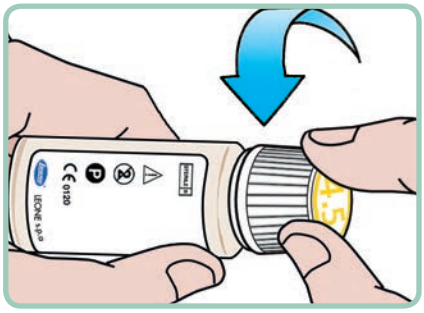
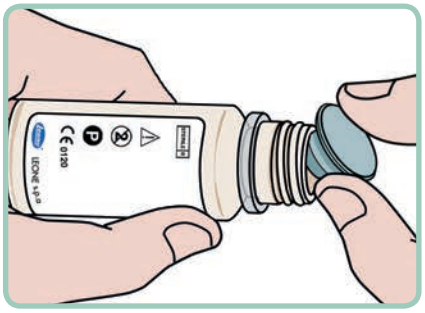
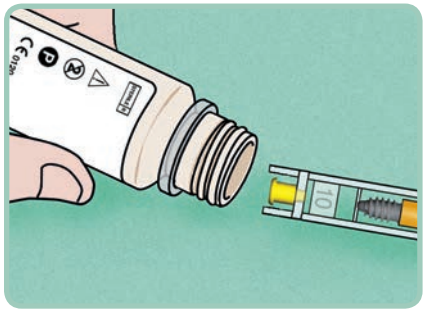
2) LEONE MAX STABILITY IMPLANTS Ø 3.75 - 4.5: PLACEMENT OF THE IMPLANT



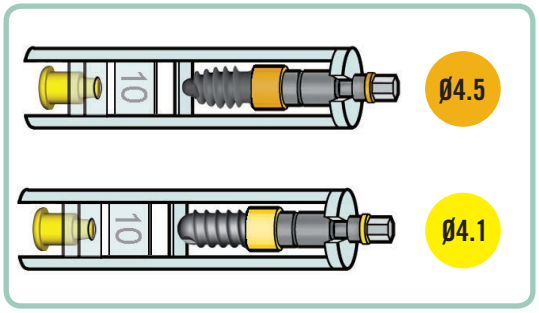
2.1 Unscrew the glass vial's top lid.



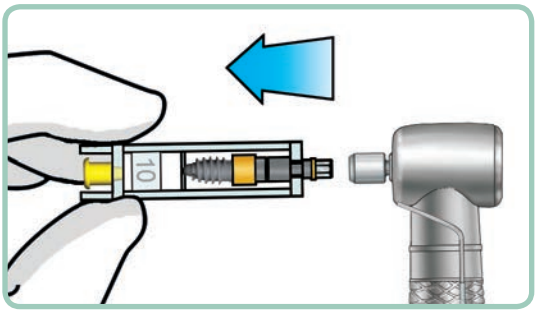
2.2 Remove the sealing cap.



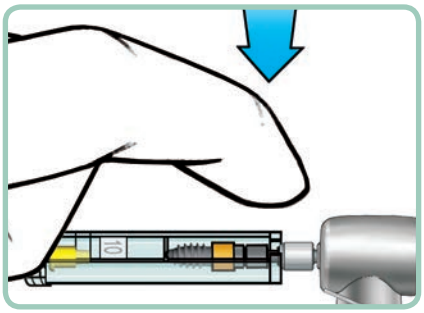
2.3 Extraction of the holder containing the implant and the cover cap on a sterile pad.

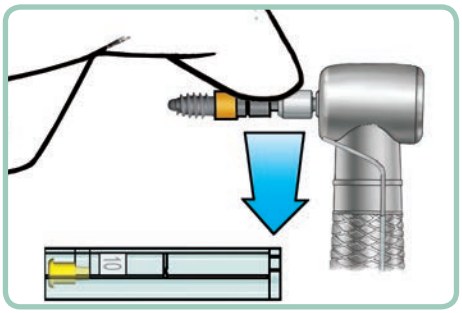


2.4 The connecting ring and the carrier's rubber ring are produced in a darker colour in order to distinguish the **LEONE Max Stability** implants from the cylindrical **LEONE** implants with the same length and connection size.

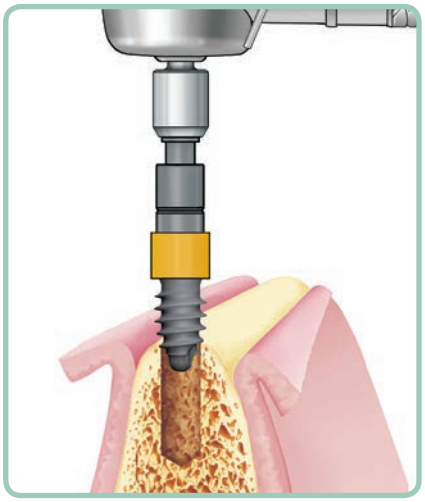


2.5 Connection of the handpiece adapter Cat. 156-1002-01 to the carrier of the implant. The use of the handpiece ensures maintenance of the implant site axis during the implant insertion in the prepared site.





2.6 Extraction of the implant from the holder by exerting a pressure on the open side in order to detach the implant and make the holder fall down.



2.7 Initial seating of the implant into the implant site. If there is not enough space for a direct connection between the carrier and the handpiece adapter, the extension Cat. 156-1002-00 may be used.

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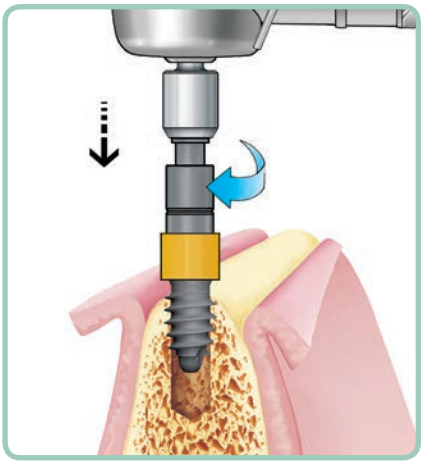
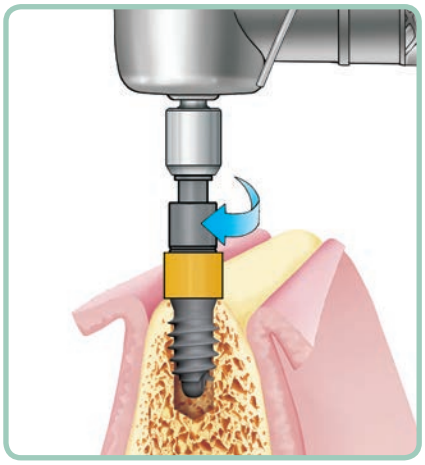
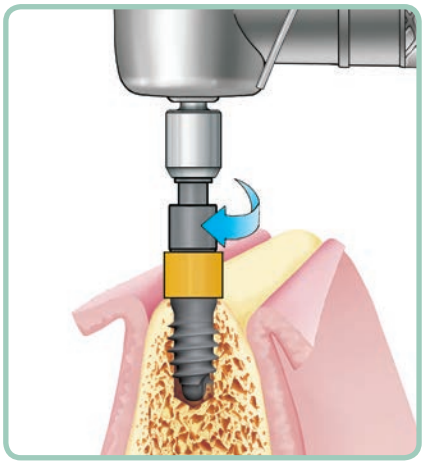


2.8 Insertion of the implant with a dental micromotor. Set a micromotor's maximum speed to 20 rpm and a maximum torque value to 50 Ncm. Insert the implant without irrigation.

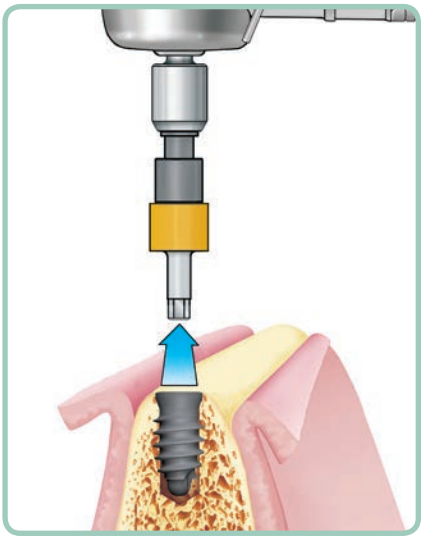


2.9 While driving the implant into the implant site, the rubber ring slides up along the carrier.



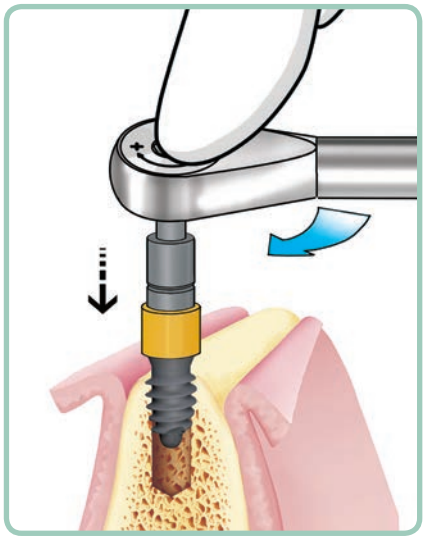
2.10 When the carrier's rubber ring has reached the reference line, the implant is exactly positioned at the level of the alveolar crest. Now the carrier can be easily disconnected from the implant.

CAUTION: ***the geometry of the LEONE Max Stability implant apex allows the implant to be inserted beyond the depth of the prepared site. Therefore, special attention should be paid to reaching the planned placement level related to the bone crest.***



2.11 Removal of the carrier from the implant.

2.12 Rinsing and drying of the implant's inner side before placing the cap.



2.13 If the maximum torque value of 50 Ncm is not enough to complete the insertion of the implant, remove the handpiece adapter from the carrier and attach the ratchet Cat. 156-1014-00. Be sure the instrument is directed in the long axis by gentle pressing the head of the instrument with a finger.

2.14 Should a ratchet be utilized, the forces exerted on the implant and on the correspondent peri-implant bone can become excessive. In this eventuality, should a value of 60 Ncm be exceeded, a torque limiting device will cause a fracture above the connection with the implant; now the carrier can be removed. Note that carrier fracture is not always visually perceptible, but is detectable by a sudden loss of functionality of the insertion instrument accompanied by a sharp crack.

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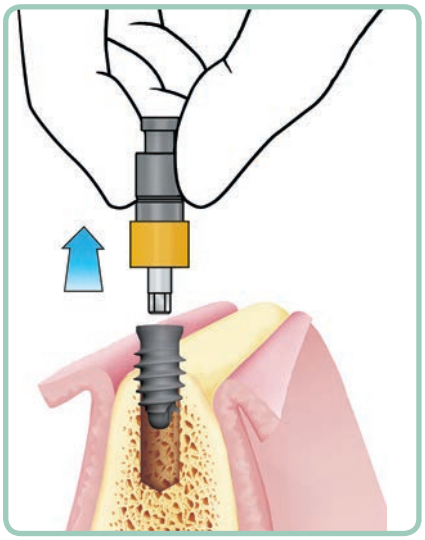
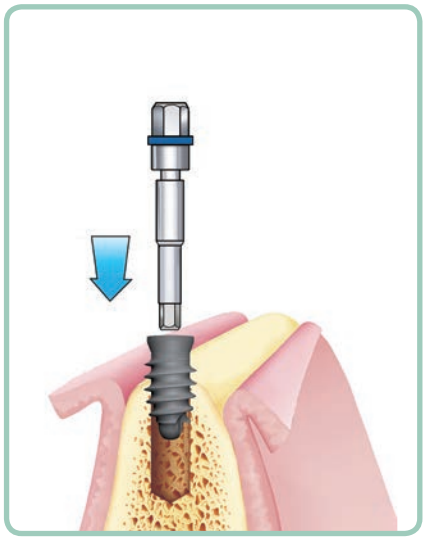
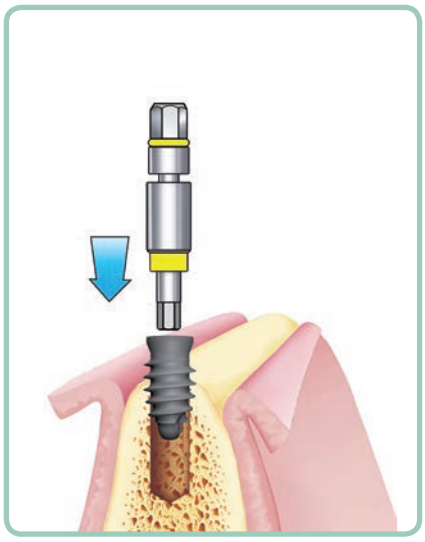


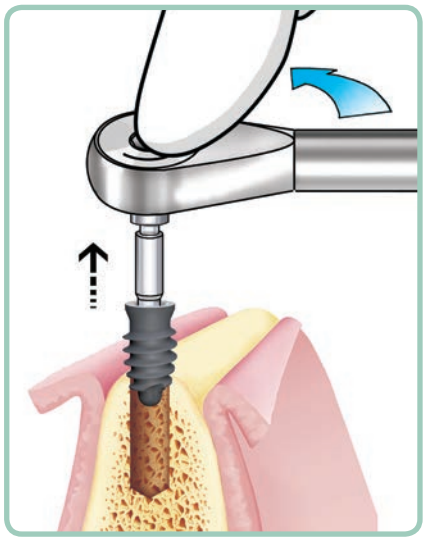
2.15 Removal of the fractured carrier.



2.16a Replace the carrier with the implant driver (Cat. 156-1013-00 available either in the surgical kit or in the specific organizers) withstanding an applied torque of up to 140 Ncm.



2.16b It is possible to use special drivers specific for each connection size, which are more stable thanks to the conical support ring and thus more resistant to the application of bending forces.



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

2.18 Use the twist drill for hard bone of the diameter corresponding to the implant (see point 1.13). Then reinsert the implant using the micromotor, repeating steps 2.7-2.11.

CAUTION: Should it still be difficult to insert the implant after the use of the twist drill for hard bone, do not use the LEONE Max Stability implant because the bone density of the implant site is too high and does not comply with the indications for use of this implant.
*We recommend placing a cylindrical **LEONE** implant with the same length and connection size.*

For the following steps: Implant closure, Second stage surgery, Soft tissue conditioning, Prosthetic procedure, refer to the indications for the **LEONE** Implant System (pages 63..70 and 79), taking into consideration the following implant connection sizes:
Ø3.75 mm implant: same connection as the Ø3.3 mm **LEONE** implant (colour code: GREEN)
Ø4.5 mm implant: same connection as the Ø4.1 mm **LEONE** implant (colour code: YELLOW).

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