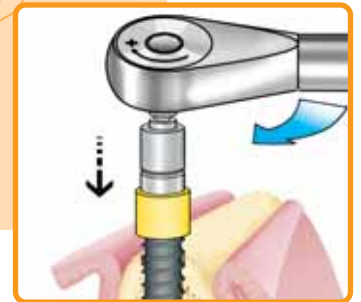
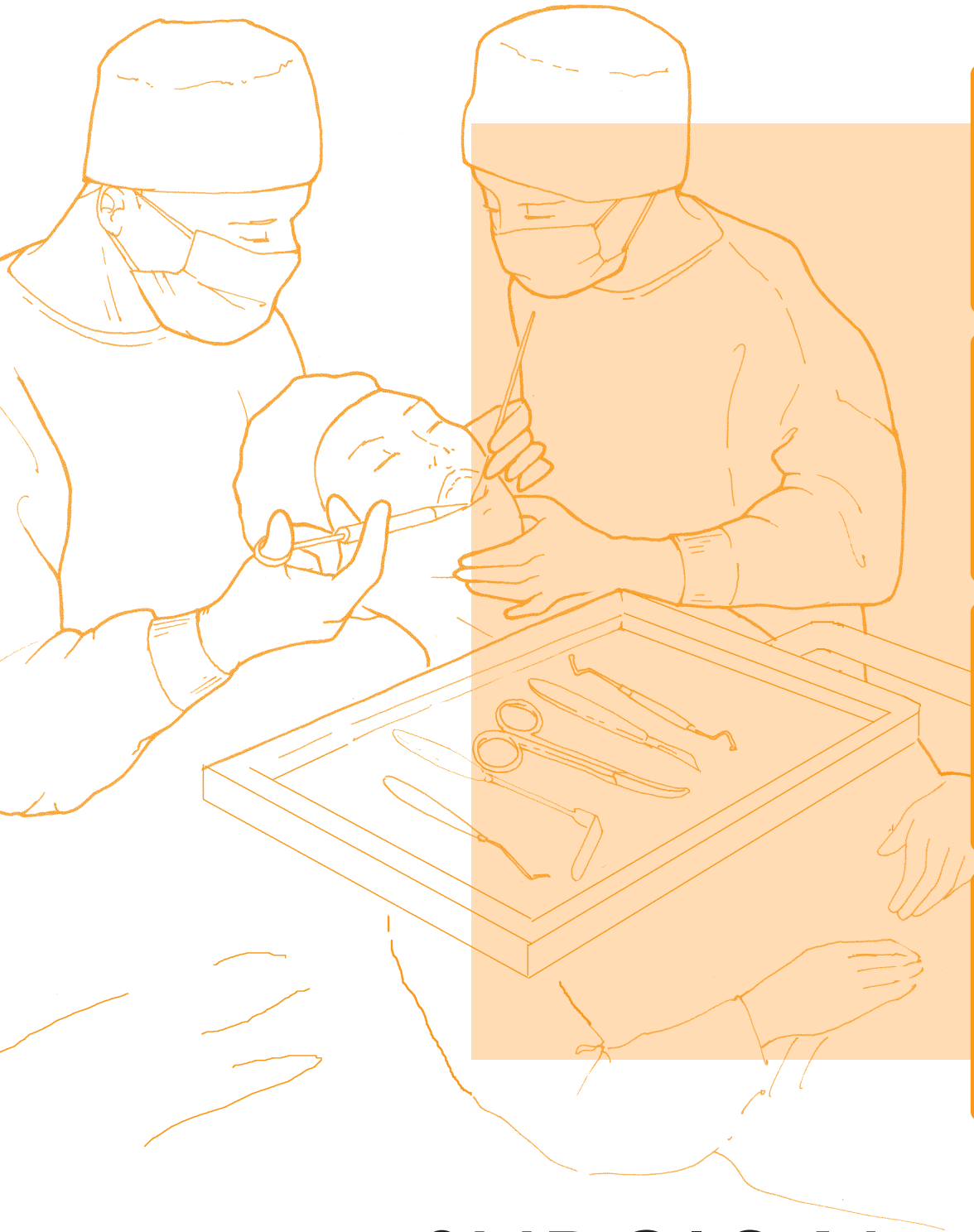


LEONE EXACONE™ IMPLANT SYSTEM



SURGICAL PROCEDURE

DISCLAIMER

The Surgical Procedure and the use of the products of the Leone EXACONE™ 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 the implant system.

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 EXACONE™ 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.

IMPLANTO-PROSTHETIC 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.

PRE-OPERATORY 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, inter-arch 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 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 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 prosthetical restoration
6. type of the surgical procedure followed

Further and particular single situations must be evaluated by the clinician.

A template Cat. 156-2003-00 (page 29) is available that shows all Leone **EXACONE™** 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.

*We advise **not** to seat a single implant 3.3 mm diameter in molar position.*

The implant of 3.3 mm in diameter, length 8 mm, must be used as an implant support in the prosthesis composed of two or more implants of any diameter and length. The positioning of all implants above the crestal bone edge is not advisable.

SURGICAL KIT AND ORGANIZER

The surgical kit, (pages 30, 31), completely autoclavable, contains all the necessary surgical instruments for the implant treatments with the LEONE **EXACONE™** Implant System.

To simplify the surgical operation, a surgical kit with reduced dimensions, an organizer (pages 32, 33) was conceived by LEONE to sterilize and hold the necessary instruments on the operating table.

The organizer is fully autoclavable and it can contain up to 8 instruments on special color coded supports.

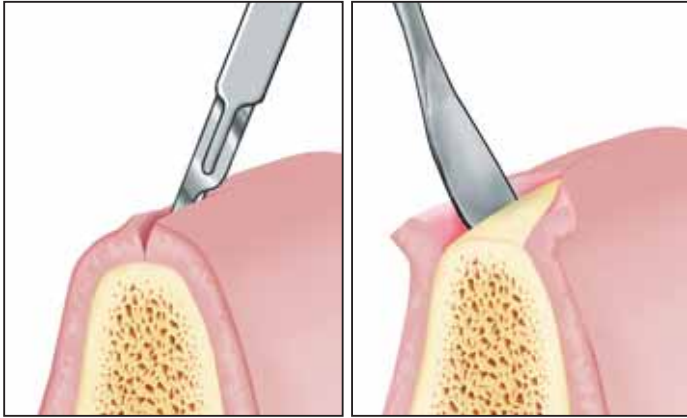
Either the organizer and the surgical kit must be wrapped and sterilized before use.

The sterilization must be done as follows:

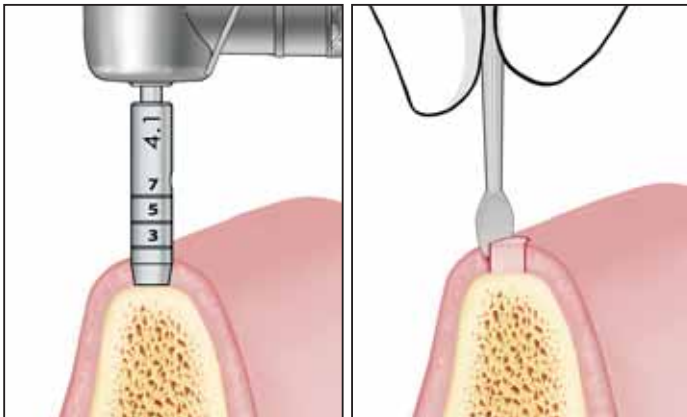
- wrap the organizer or the kit into a sterilization bag as requested by the manufacturer of the sterilizing machine;
- autoclave at 121° (250°F) for 20 minutes;
- remove the organizer from the autoclave and leave it cool inside the bag;
- leave the organizer or the kit inside the bag to preserve sterility.

1) Preparation of the implant site

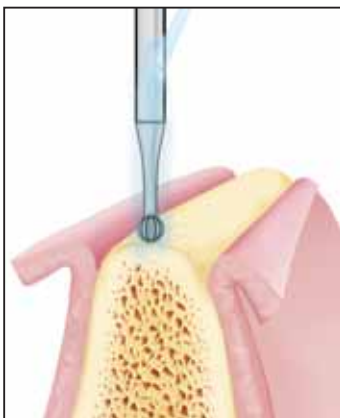
The typology and the access to the surgical site shall be selected by the professional according to the clinical-morphological parameters. Schematically and with illustrative purpose only, the following steps for the preparation of the implant site are illustrated.



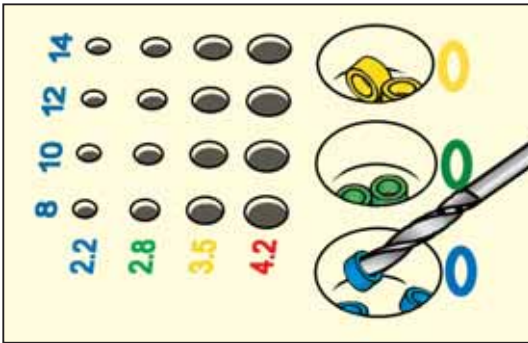
1.1a Full-thickness incision of the soft tissues and detachment of the gingival flaps to have access to the bone ridge.



1.1b If flapless procedure is followed, use the circular mucosa punch for contra-angle of the same diameter of the implant. Set the handpiece to low speed (approx. 40 rpm). Drill down until bony tissue is met. For visual reference, as well as 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. Detachment of the gingival flap by using a small periosteal elevator.

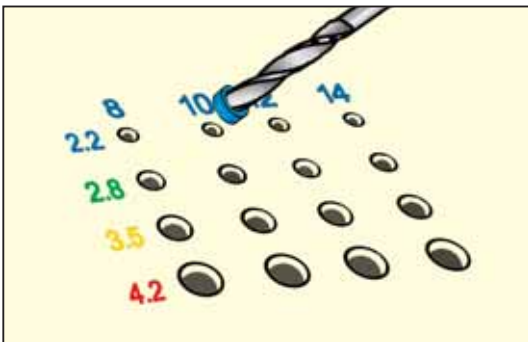


1.2 Use of the round bur to create a guidance for subsequent drills on the cortical surface of the bone.

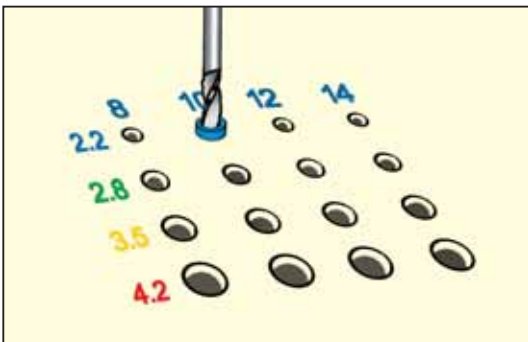


1.3 The use of depth gauges is recommended to detect the depth of every drill's job. The depth gauges are ringlets of elastomer, for single use, manufactured in the color code proper of every implant diameter.

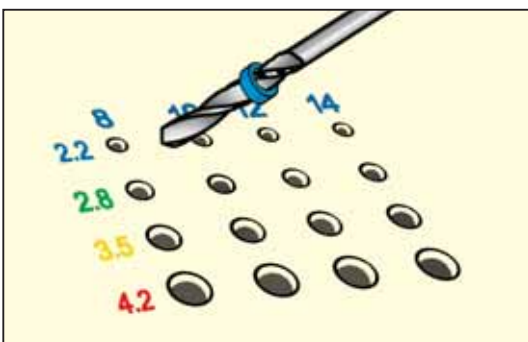
The depth gauges and the special positioner (Cat. 151-0001-00 page 22) included in the kit or single supplied must be sterilized by autoclave before use. Choose the depth gauge matching the diameter of the drill to be used (pilot drill 2.2 mm diameter blue colour, twist drill 2.8 mm diameter green colour, twist drill 3.5 mm diameter yellow colour, twist drill 4.2 mm diameter red colour). Seat the ringlet on the tip of the drill.



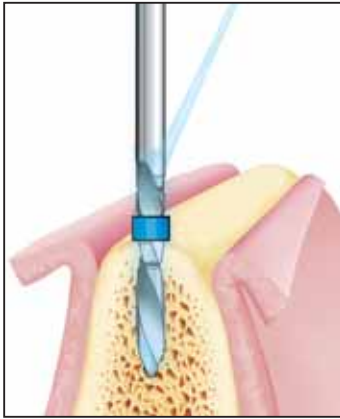
1.4 Placement of the drill in the hole corresponding to the diameter of the instrument and the selected depth.



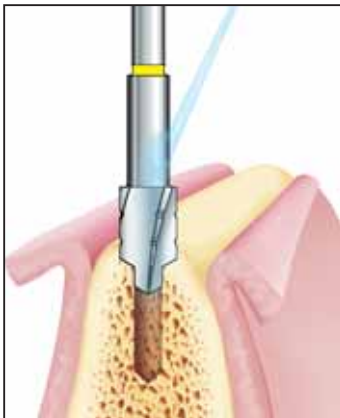
1.5 Bring the drill to full rest.



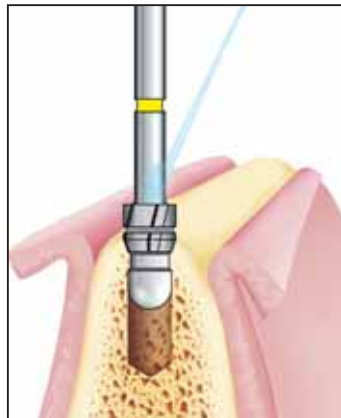
1.6 In this way the depth gauge will exactly be positioned in correspondence to the notch for the selected depth.



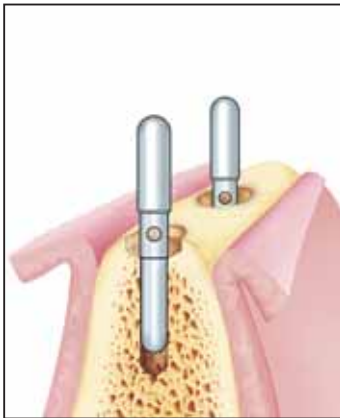
1.7 Use of the pilot drill (diameter 2.2 mm): seat the drill up to the marked notch, which corresponds to the length of the selected implant.
(Max Speed: 800 rpm. flushing with water adequately)



1.8a Use of the stepped drill with the same dimensions of the selected implant for the creation of the housing for the implant neck up to the first notch.
(Max Speed: 300 rpm. flushing with water adequately).



1.8b As an alternative, it is possible to drop the use of the stepped drill and when the augmentation sequence of the implant site by means of the twist drills is over (see point 1.11), use the countersinking tool with the same diameter as the selected implant, up to the reference indent.
(Max. speed: 300 rpm. flushing with water adequately)



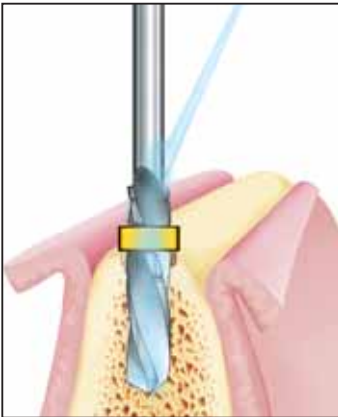
1.9a Use of paralleling pins for the control of parallelism with natural teeth and/or other adjacent implant sites. A radiographic exam can be performed to increase accuracy in the evaluation of parallelism. The paralleling pin can also be utilized after the application of a 2.8 mm diameter drill, taking 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.



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.



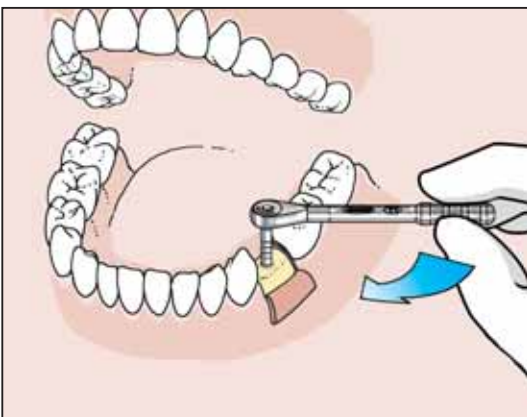
1.11 Widening of the diameter of the implant site by progressive use of drills with increasing diameter. The drills have to be seated also with the aid of depth gauges up to the notch which correspond to the length of the selected implant with the aid of the depth gauges too:

- for implants with 3.3 mm diameter: use drill with 2.8 mm diameter. *Max Speed: 600 rpm.*
- for implants with 4.1 mm diameter: after 2.8 mm drill, use the drill with 3.5 mm diameter for the final resizing of the site. *Max Speed: 500 rpm.*
- for implants with 4.8 mm diameter: after using 2.8 mm and 3.5 mm drills, use the drill with 4.2 mm diameter for the final resizing of the site. *Max Speed: 400 rpm.*

Reminder: flush with water when using drills



1.12 In case of high bone density, the use of the reamer is recommended. With medium/low bone quality the EXACONE™ implant can be self-threaded.



1.13 The tap can be connected to the handpiece screwdriver, to the angled key or to the ratchet. When the space for the direct connection between the tap and the instruments is insufficient, the extension for the hand screwdriver Cat. 156-1002-00 can be utilized. Tapping operations can be also performed by means of a handpiece for implantology connecting the tap with the special adapter Cat. 156-1002-01.

2) Implant packaging



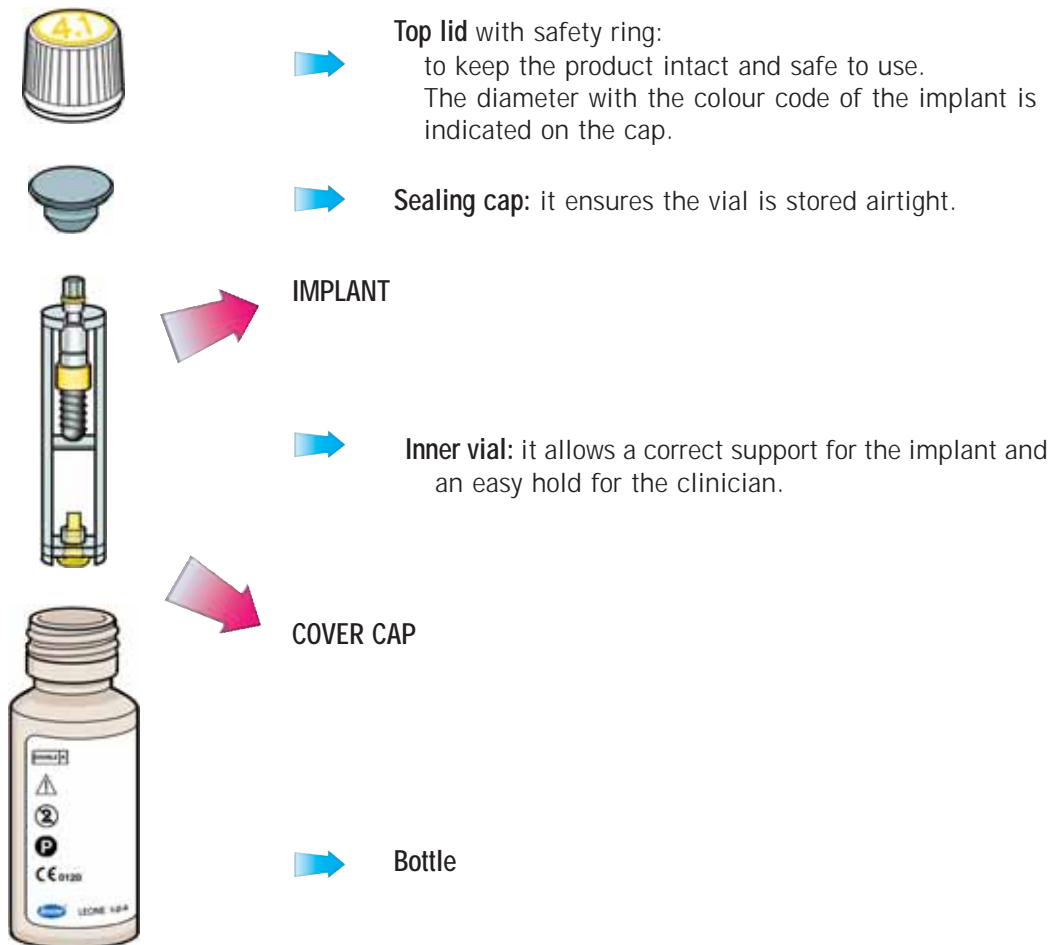
2.1 The packaging

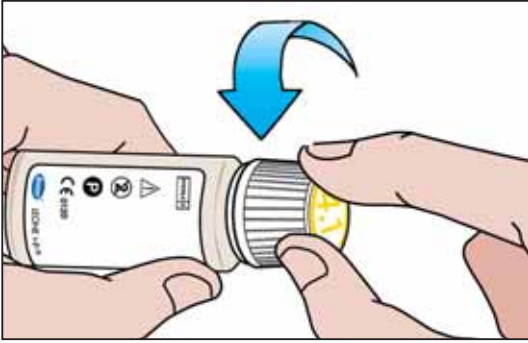
The packaging features a double protection to preserve the sterility of the implant subjected to a certified gamma x-ray process.

A removable part of the label showing the information of the implant (see label symbols at page 100) is to be applied on the "Identity card" of the implant or on the clinical case sheet of the patient.

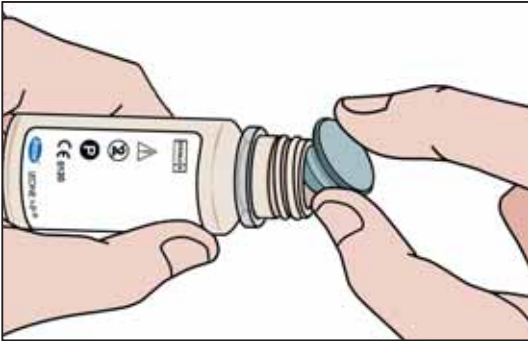
A sterility indicator is present on the bottle.

2.2 The bottle

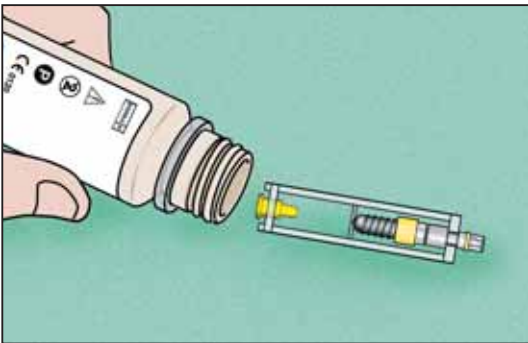




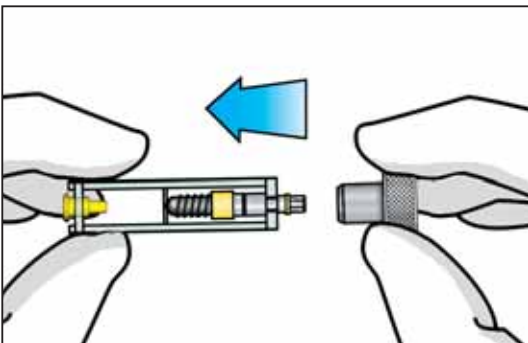
2.3 Unscrew the bottle's top lid.



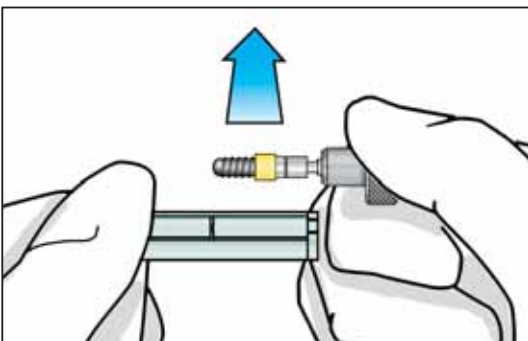
2.4 Remove the sealing cap.



2.5 Extract the vial containing the implant and the cover cap on a sterile pad.

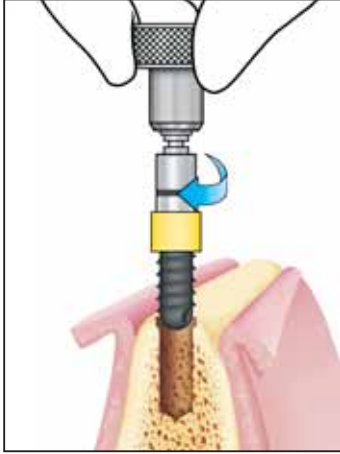


2.6 Connection of the hand screwdriver to the carrier of the implant. The hand screwdriver presents a hole for the placement of a safety leash.



2.7 Extraction of the implant from the open side of the vial by means of the hand screwdriver. Take care to exert the extraction parallel to the longitudinal plan of the vial. 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.

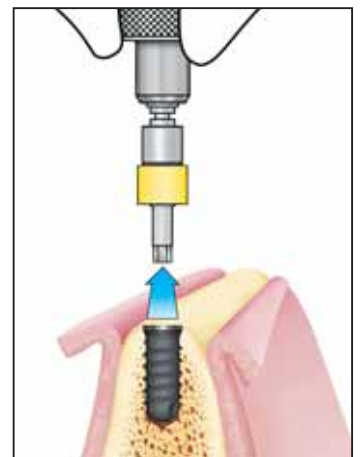
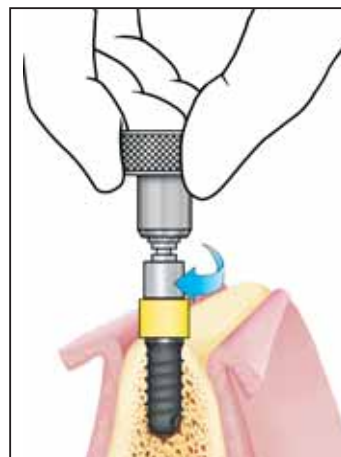
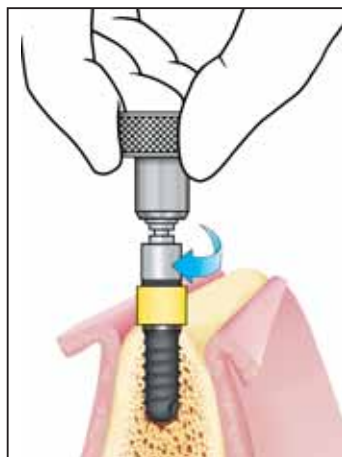
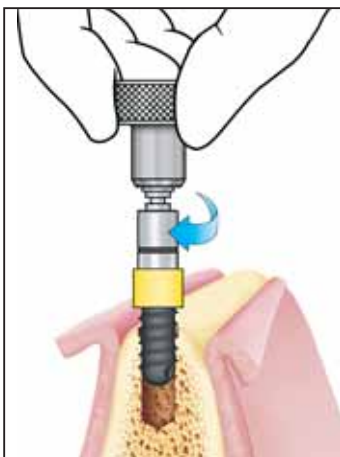
3) Placement of the implant



3.1 Initial placement of the implant in the implant site.
Should there not be enough space for the direct connection between carrier and the screwing instruments, the extension for hand screwdriver Cat. 156-1002-00 can be used.

3.2 The carrier is disconnected from the implant when the implant has reached the level of the alveolar crest (the rubber ring of the carrier has reached the reference line).

The carrier provides a handle for the grasp of the implant without compromising the sterility. It also allows the correct positioning of the implant at the level of the alveolar crest due to the presence of a rubber ring at the connection between the carrier and the implant: **exclusive LEONE method.**



The carrier allows initial placement of the implant into the implant site.

During the placement of the implant into the implant site, the rubber ring slides up along the carrier.

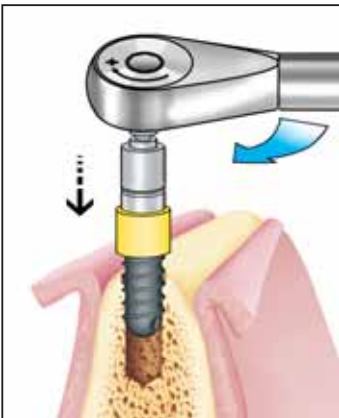
The arrival of the rubber ring at the reference line indicates that the implant has been exactly positioned at the level of the alveolar crest.

Remove the screwdriver. At this point the carrier can be easily disconnected from the implant. During this phase, which is very delicate, no uncontrolled forces are applied.



3.3 Screw the implant with a hand screwdriver.

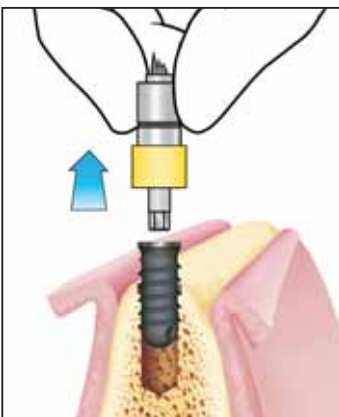
The placement of the implant can also be effected with a handpiece by using the special adapter Cat. 156-1002-01.



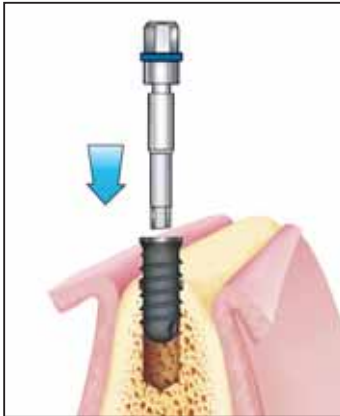
3.4 Should a ratchet or an angular key be utilized, the forces exerted on the implant and on the correspondent peri-implant bone can become excessive.



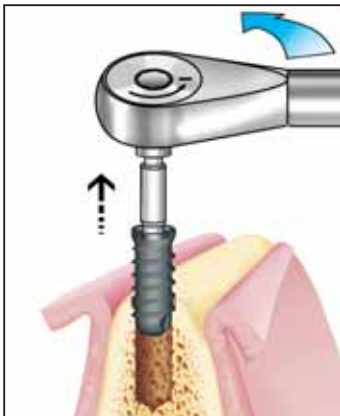
3.5 In this eventuality, should 60 Ncm be overcome, a torque limiting device make the carrier break above the connection with the implant; now the carrier can be removed.



3.6 Removal of the fractured carrier.



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

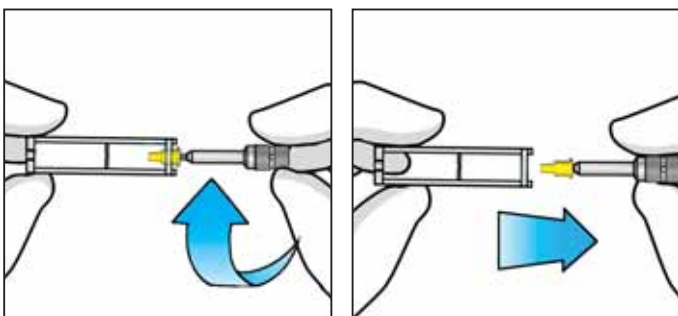


3.8 Removal of the implant from the implant site. Tapping and new placement of the implant.

3.9 Rinsing followed by drying of the inside of the implant before placing the cover cap.

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

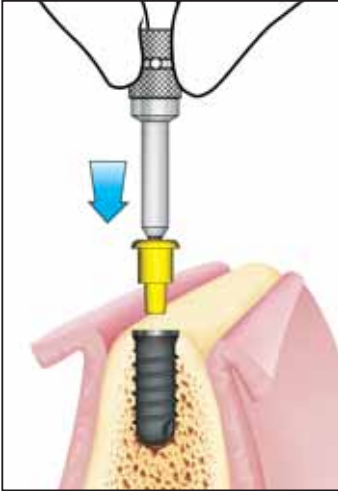
4) Two-stage surgical procedure: first stage



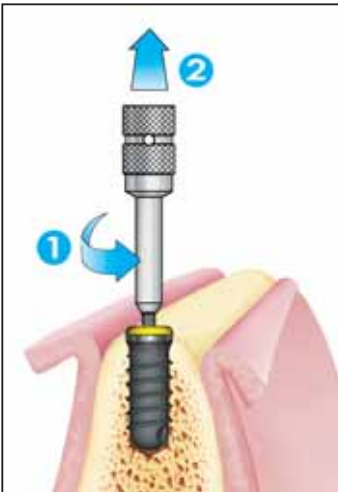
4.1 Take the vial that previously contained the implant. Screw the cap instrument, Cat. 156-1003-00, on the head of the cover cap. The cap instrument presents a hole for the placement of a safety leash. Removal of the biopolymer cover cap from the special support by a slight extraction.



4.2 In case of positioning of several implants, the colour-coded cap allows an immediate identification of the correct diameter.



4.3 Positioning of the cover cap over the implant: push the cap home inside the implant.



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



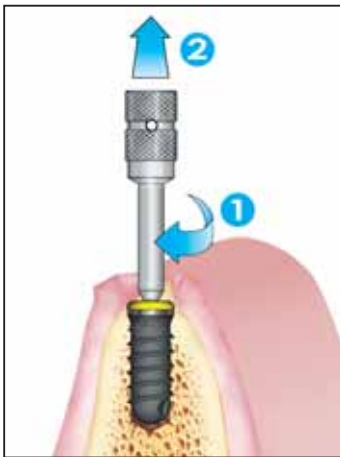
4.5 The gingival flaps are sutured for total coverage of the implant.

The average time period for the attainment of a good osteointegration (which is facilitated by the HRS™ surface that covers all LEONE EXACONE™ implants) is about 3 months. This time period may vary, however, up to 8 months according to the type of surgical intervention, the quality of the bone, the individual response of the patient. Clinical checks and instrumental exams are absolutely necessary.

5) Two-stage surgical procedure: second stage

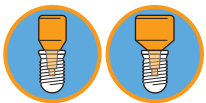


5.1 When osteointegration has occurred, the position of the implant is identified and an incision of the soft tissue covering the implant is performed.

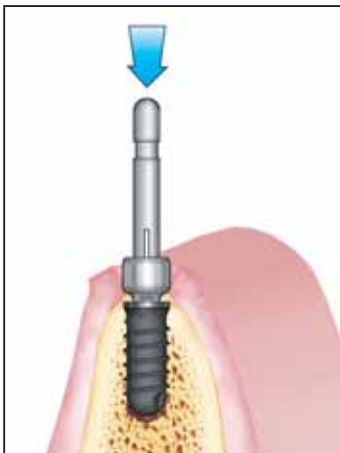


5.2 Removal of the cover cap with the specific extractor Cat. 156-1003-00 that is supplied in the surgical kit or in the instrument organizer. The extractor must be screwed into the head of the cover cap in order to exert the traction force that is necessary to remove the cap.

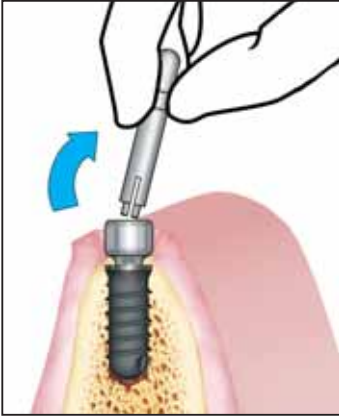
5.3 Accurate rinsing followed by drying of the inside of the implant.



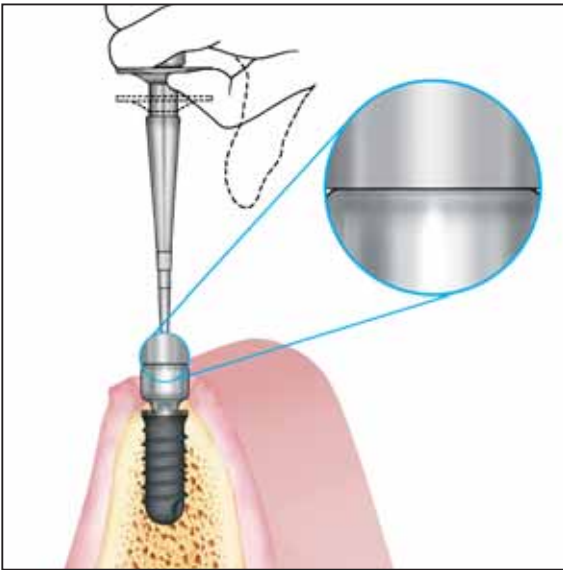
6) Two-stage surgical procedure: conditioning of the soft tissues for standard and large platform



6.1 The appropriate healing cap is placed on the implant by means of the carrier that is supplied in the sterile package. Pressure is exerted on the carrier.



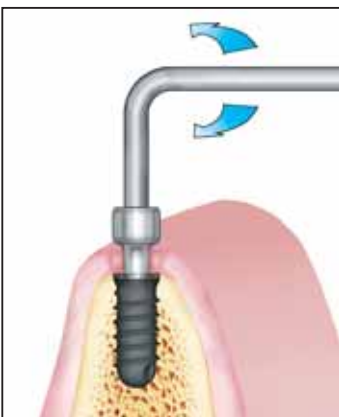
6.2 Removal of the carrier with a slight side bending of the same and following traction.



6.3 Percussion on the cap by means of the specific rod and hammer (page 28) to activate the cone connection. Two consecutive percussions are advisable.



6.4 The soft tissues around the healing cap are sutured.

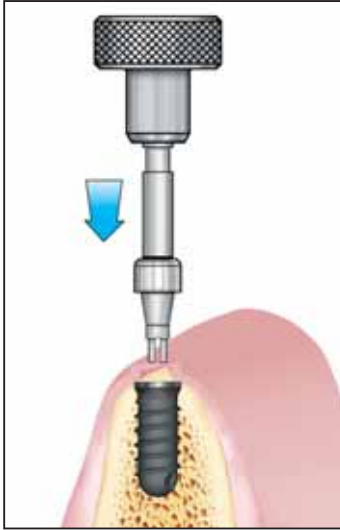


6.5 When the healing process has occurred, the healing cap is removed by means of the specific extractor with hexagonal head, Cat. 156-1006-00. The extractor, with a hole for the placement of a safety leash, is seated in the hexagon on the head of the healing cap and rotated subsequently, either clockwise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

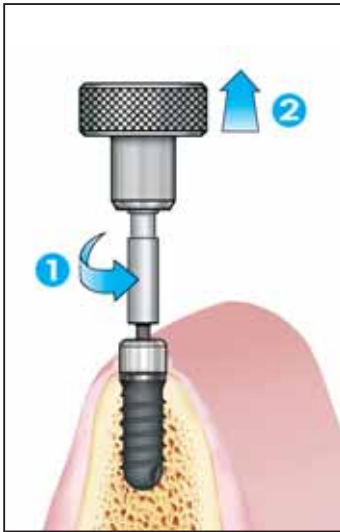


7) Two stage surgical procedure: conditioning of the soft tissues for slim platform

For previous phases refer to chapters 1), 2), 3) 4) and 5).



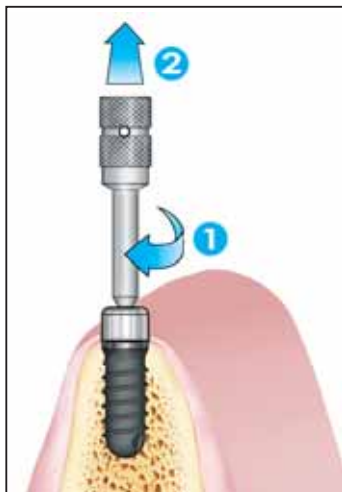
7.1 Positioning of the healing cap on the implant by means of the special carrier (sterile supplied) eventually connected with a hand screwdriver to facilitate its taking. When its hexagonal shape is engaged, exert a pressure on the cap to get a perfect closure of the implant.



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



7.3 The soft tissues around the healing cap are sutured.



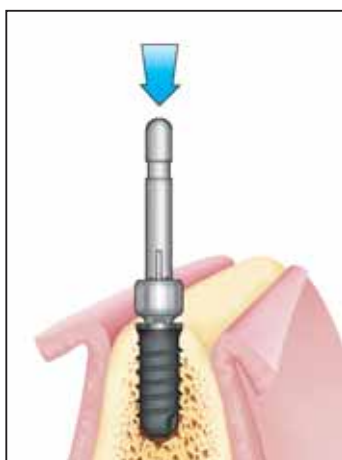
7.4 When the healing process has occurred, the healing cap is removed by means of the specific extractor for caps Cat. 156-1003-00 which is provided in the surgical kit or in the instrument organizer. The instrument for caps has to be screwed in the head of the healing cap to be able to practice enough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

For the taking of the impressions, the preparation of the abutment, and the manufacturing of the final prosthesis, refer to the "Prosthetic Procedure of the Leone EXACONE™ Implant System".

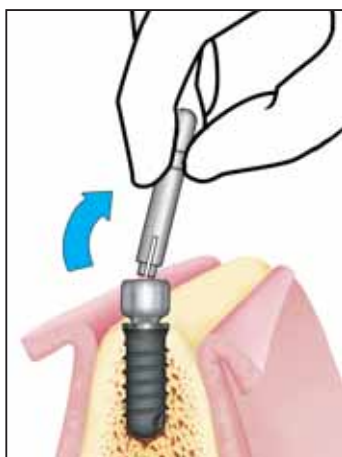


8) One-stage surgical procedure for standard and large platform

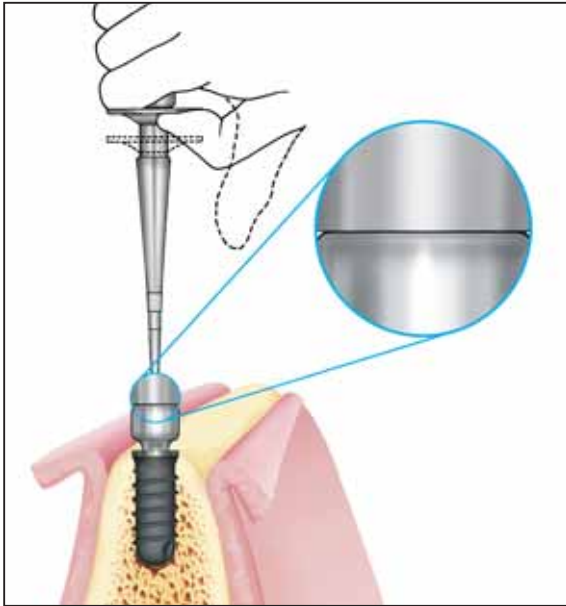
For previous phases refer to chapters 1), 2), and 3).



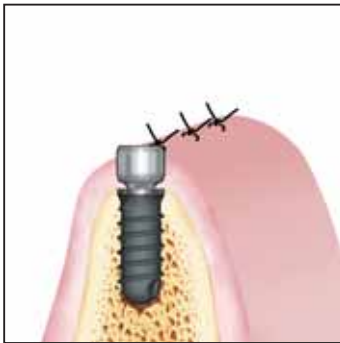
8.1 Closure of the implant by placement of the healing cap by means of the carrier sterile provided. Exert some pressure on the carrier.



8.2 Removal of the carrier with a slight side bending and following traction.



8.3 Percussion on the cap by means of the specific rod and hammer to activate the cone connection. Two consecutive percussions are advisable.



8.4 The soft tissues around the healing cap are sutured.

The average time period for the attainment of a good osteointegration (which is facilitated by the HRS™ surface that covers all LEONE EXACONE™ implants) is about 3 months. This time period may vary, however, up to 8 months according to the type of surgical intervention, the quality of the bone, the individual response of the patient. Clinical checks and instrumental exams are absolutely necessary.



8.5 When osteointegration has occurred remove the healing cap by means of the specific hex head extractor Cat. 156-1006-00. The extractor is seated in the hexagon which is present on the head of the healing cap and rotated subsequently, either clockwise or anti-clockwise indifferently, in order to extract the healing cap. The extractor presents a hole for the placement of a safety leash. By using a plier, the cap is removed from the implant. The implant is now ready for the prosthetic procedure.

For the impression taking, the preparation of the abutment, and the manufacture of the final prosthesis, refer to the "Prosthetic Procedure" of the Leone EXACONE™ Implant System.

9) Low self-locking caps: instructions for use and procedure

Premise

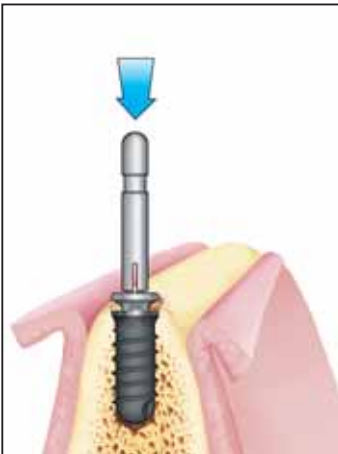
The low self-locking caps are used in several ways:

- a) During the two-stage surgery technique in replacement of the closing caps (see point 4.5) in case of post-extraction or endocrystal position as a guarantee of the microbiological seal.
- b) During the two-stage surgery technique in replacement of the healing caps (see chapter 6) in case of low gingival thickness.
- c) During the one-stage surgery technique in replacement of the healing caps (see chapter 8) in case of low gingival thickness.

a) Two-stage surgery technique: first phase with endocrystal implant position



9.1a First surgery phase: the implant is seated below the osseous crest.



9.2a Positioning of the low self-locking cap on the implant with the sterile positioner. Follow instructions given at points 6.2 and 6.3.

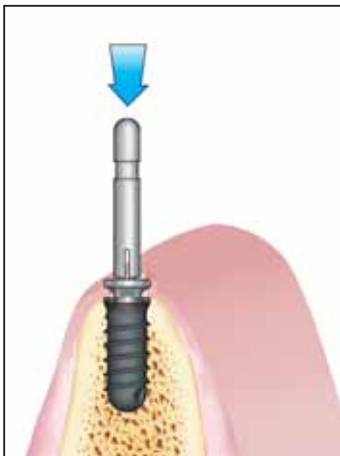


9.3a The gingival flaps are sutured for total coverage of the implant. When osteointegration has occurred, follow instructions at points 5.1 and 6.5.

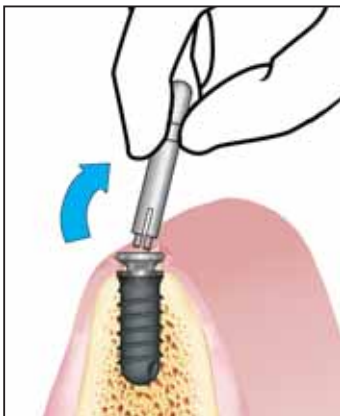
b) - c) Conditioning of soft tissues with low gingival thickness



9.1b - 9.1c The implant is now at osseous crest level.



9.2b - 9.2c Positioning of the low self-locking cap on the implant with the sterile positioner.



9.3b - 9.3c Remove the positioner with a slight side bending and following traction.
In case of two-stage surgical procedure follow instructions at points 6.3-6.5
In case of one-stage surgical procedure follow instructions at points 8.3-8.5.



10) Overdenture: two stage surgical procedure for standard platform

Premise

Abutments for O-ring overdenture and overdenture with bar are available.

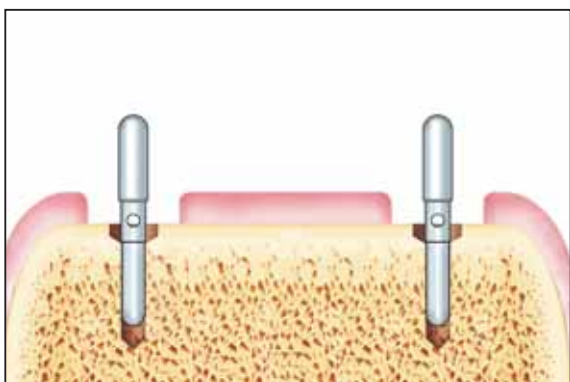
In order to manufacture an overdenture, a perfect parallelism between the implants is necessary.

Preferably overdentures are manufactured with a minimum of 2 and a maximum of 4 implants.

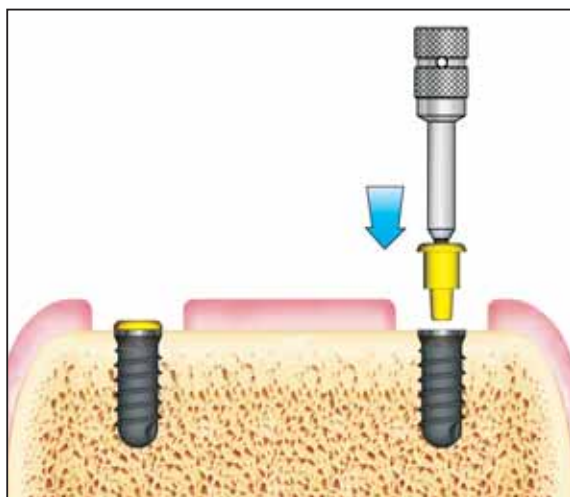
The two-stage surgical procedure, as described in chapters 4), 5), 6), is recommended.

It is possible to manufacture an overdenture with a new or a pre-existing prosthesis, the second case must be evaluated by the clinician.

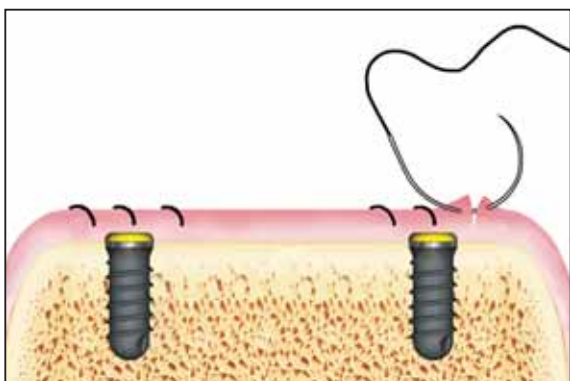
The herewith graphical illustrations refer to the placement of two implants in the mandible.



10.1 Preparation of the implants sites, with special care for parallelism.

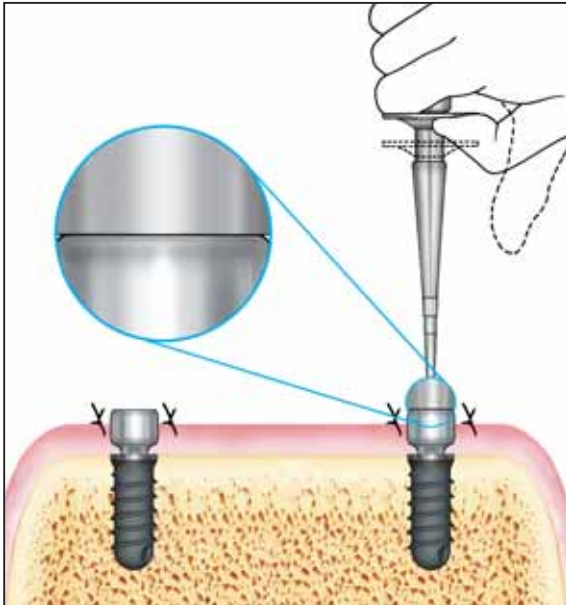


10.2 Closure of the implants with placement of the cover caps.

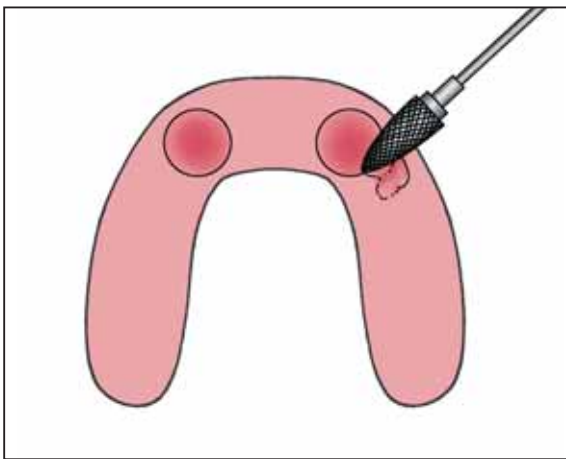


10.3 The gingival flaps are sutured for total coverage of the implants. It is recommended to wait several days before using a temporary prosthesis or the pre-existing prosthesis of the patient. The resin of the prosthesis, however, must be removed in the area of the implants and rebased with soft resin.

10.4 After the attainment of a good osteointegration of the implants, the sites are opened again and the cover caps are removed.



10.5 The healing caps are seated for the conditioning of the soft tissues. Two consecutive percussions are advisable.



10.6 The temporary or pre-existing prosthesis is re-adapted with removal of the resin in the areas corresponding to the healing caps.

10.7 Upon healing of the soft tissues, the final overdenture may be manufactured.

For the manufacturing of the final prosthesis, refer to the "Prosthetic Procedure of the Leone Exacone™ Implant System".