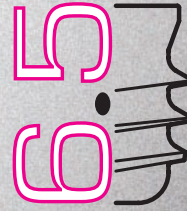
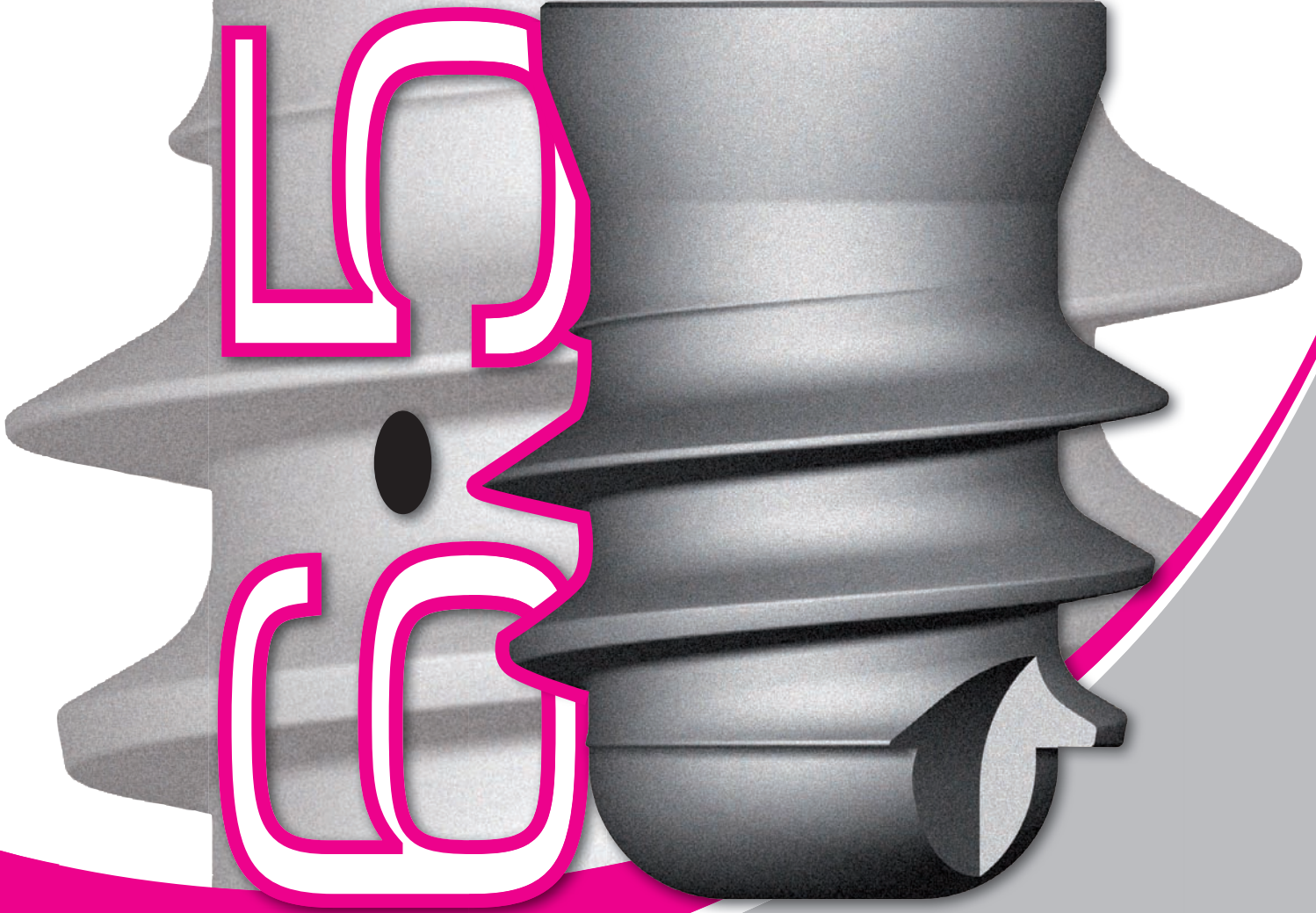


~~EX~~ACONE™

LEONE
SHORT
IMPLANT



ORTHODONTICS and IMPLANTOLOGY

SURGICAL PROCEDURE

LEONE SHORT IMPLANT



SUMMARY

Surgical procedure

Disclaimer and Implanto-prosthetic treatment planning

- 1) Preparation of the implant site
- 2) The implant packaging
- 3) Placement of the implant

SURGICAL

PROCEDURE

DISCLAIMER

The Surgical Procedure for the Leone EXACONE™ 6.5 short Implant described in the following pages is 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™ 6.5 short Implant** 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: if advisable.

COMPUTER AIDED 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

Number and dimensions (diameter and length) of the implants to be seated are determined by the following factors:

1. amount of available bone
2. caratteristiche del sito implantare
3. masticatory load
4. aesthetic results
5. type of prosthetic restoration
6. type of surgical procedure

The EXACONE™ 6.5 short implant is intended for use in cases with limited vertical bone availability.

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

A special template Cat. 156-2003-02 is included in the organizer and available also as single product. It shows the **Leone EXACONE™ 6.5 short Implant** in various dimensions: in actual sizes and with dimensions increased either by 10% or by 25%, to match possible distortions created by the instrument for radiographic examinations (CT, panoramic radiograph, standard and digital cephalograms).

Lay the template upon the radiograph in order to select the implant in relation to the quantity of available bone.

ORGANIZER

The organizer, Cat. 156-0019-00, allows the clinician to sterilize and hold only the instruments necessary for the preparation of the **Leone EXACONE™ 6.5 short Implant** site ready on the operating table.

It is completely autoclavable and includes 8 devices placed on a colour-coded support.

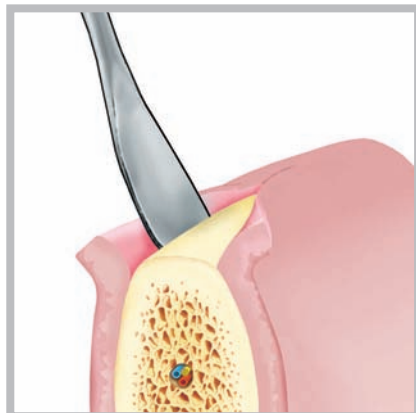
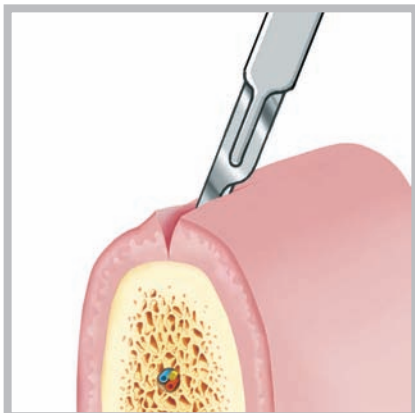
The organizer must be wrapped and sterilized before use.

The sterilization must be done as follows:

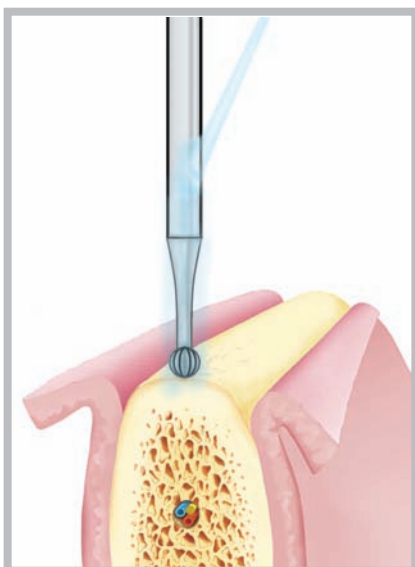
- wrap the organizer into a sterilization bag as requested by the manufacturer of the sterilizing machine;
- autoclave at 121° C (250°F) for 20 minutes;
- remove the organizer from the autoclave and leave it cool inside the bag;
- leave the organizer inside the bag to preserve sterility.

I) Preparation of the implant site

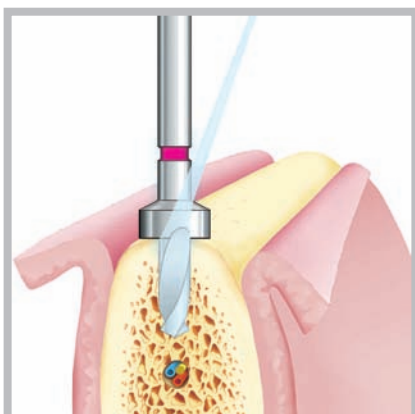
The **EXACONE 6.5 short implant** is intended for use in cases with limited vertical bone availability. The typology and the access to the surgical site shall be selected by the professional according to the clinical-morphological parameters. Schematically and with illustrative purpose only, the following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



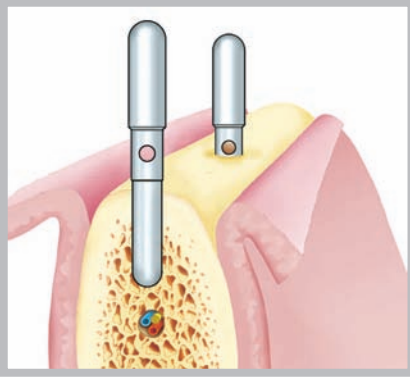
1.1 Full-thickness incision of the soft tissues and detachment of the gingival flaps to have access to the bone ridge.



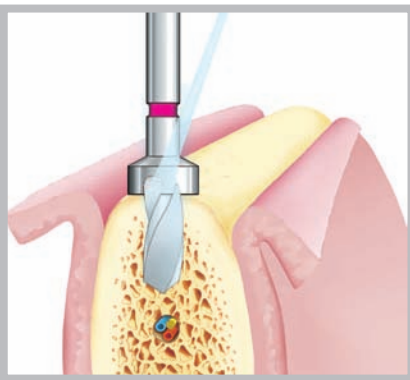
1.2 Use of the round bur Cat. 151-1934-01 to mark and slightly smooth cortical surface of the bone, thus simplifying subsequent drills' passage.



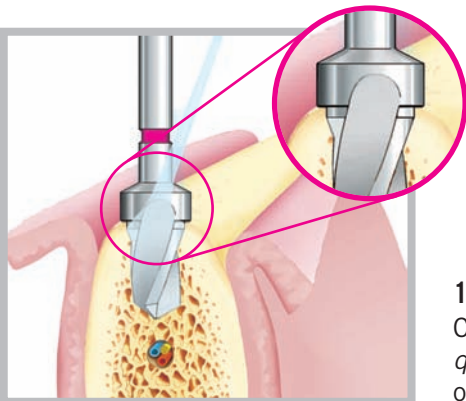
1.3 Use of the $\varnothing 2.2$ mm pilot drill with integrated stop, Cat. 151-2233-65: insert the drill up to the stop. (*Max speed: 800 rpm with adequate irrigation*).



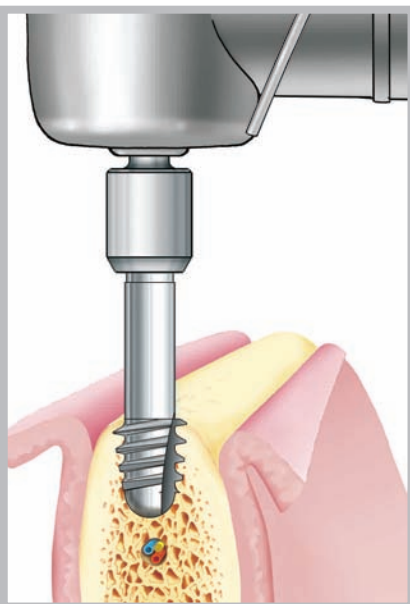
1.4 Use of paralleling pins as an aid for proper alignment with natural teeth and/or other adjacent implant sites. A radiographic exam can be performed to increase accuracy in the evaluation of parallelism. The paralleling pin can also be utilized after the application of a Ø2,8 mm twist drill with integrated 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.



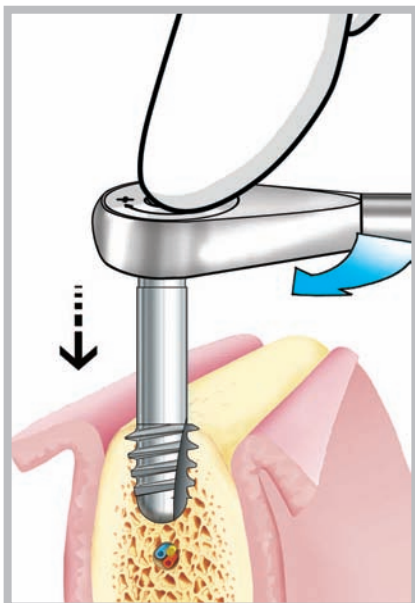
1.5 Use of the Ø2,8 mm twist drill with integrated stop, Cat. 151-2833-65: insert the drill up to the stop. (*Max Speed: 600 rpm with adequate irrigation*).



1.6 Use of the Ø3,5 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.

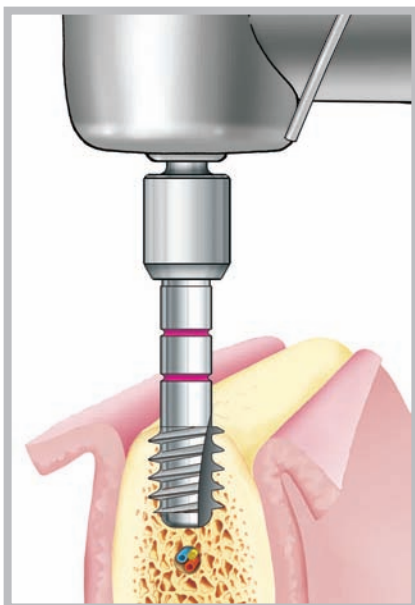


1.7a Use of the bone tap "A" Cat. 152-5021-01 in combination with the specific hand-piece adapter Cat.156-1002-01: attach the tap to the handpiece, then tap the implant site until the tap's threaded portion is totally inside the bone; the use of the handpiece ensures the maintenance of the implant site axis. Set a micromotor's *maximum speed of 30 rpm and a maximum torque value of 50 Ncm*.



1.7b 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.



1.8 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 1.7a and 1.7b. shall be repeated. The bone tap "B" can easily be distinguished from bone tap "A" by two fuchsia-coded marks on the instrument.



2) Implant packaging



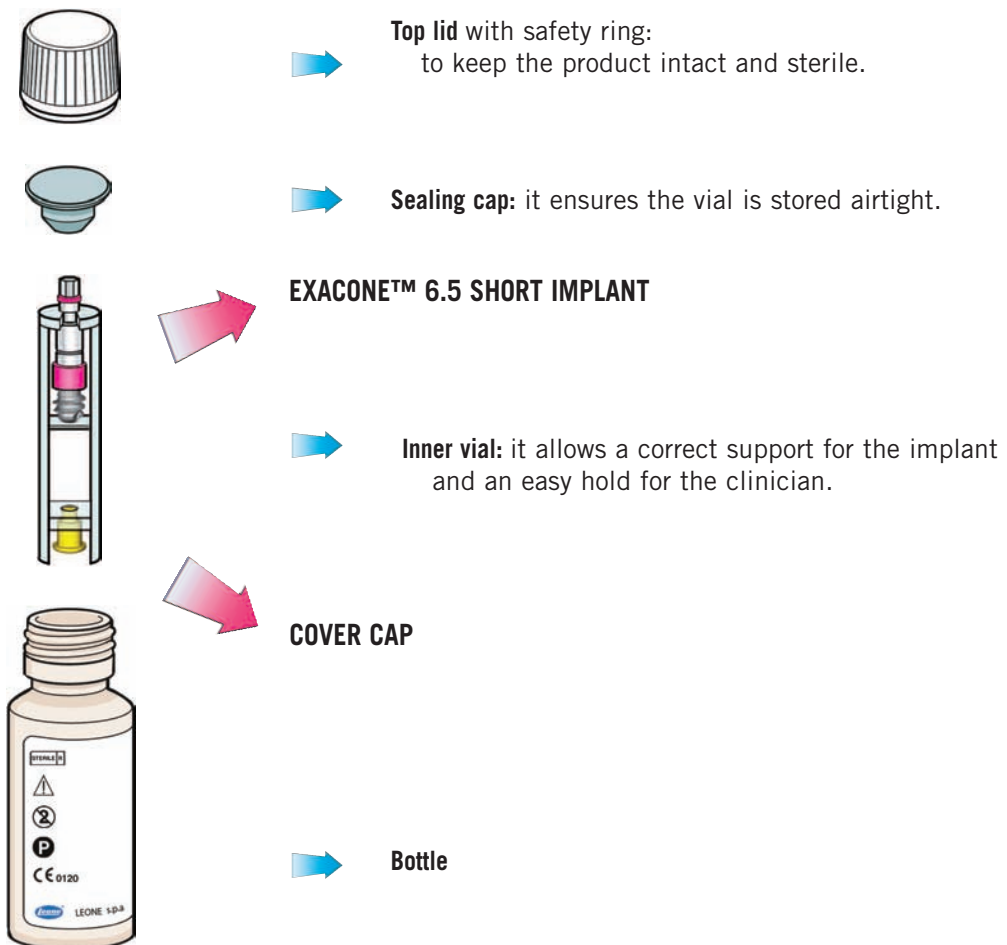
2.1 The packaging

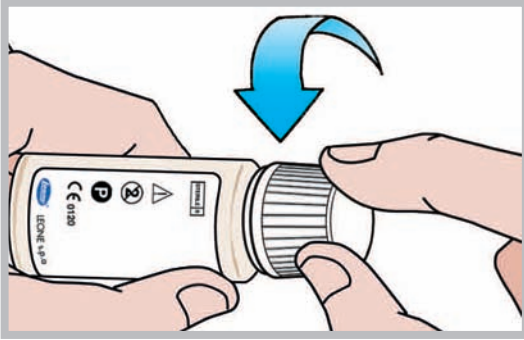
The packaging features a double protection to preserve the implant's sterility, obtained through a certified gamma x-ray process.

A removable part of the label showing implant information (see label symbols at the bottom of this procedure) is to be applied on the "Identity card" of the implant or on the patient's case file.

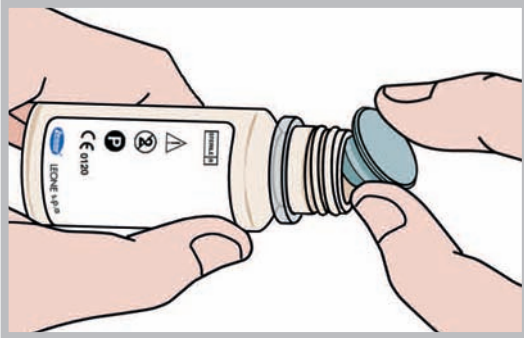
A sterility indicator is present on the bottle.

2.2 The bottle

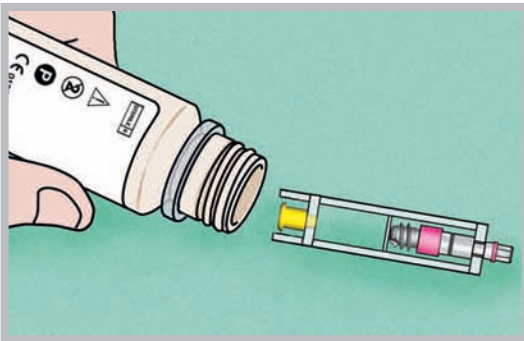




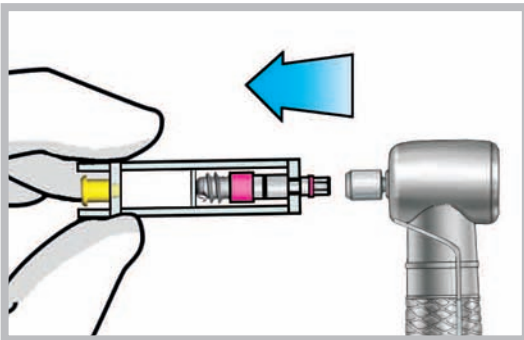
2.3 Unscrew the bottle's top lid.



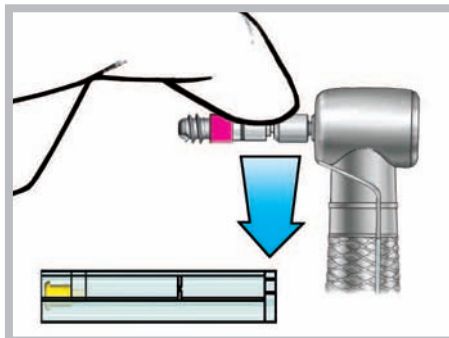
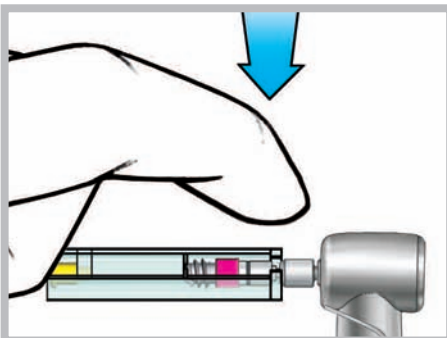
2.4 Remove the sealing cap.



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

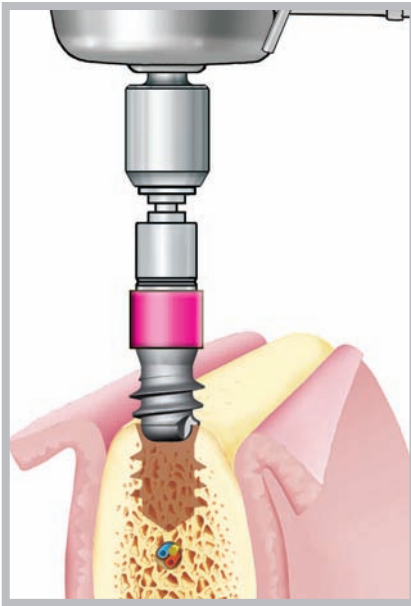


2.6 Connect the handpiece adapter Cat. 156-1002-01 to the implant carrier; the use of the handpiece ensures the maintenance of the implant insertion axis.



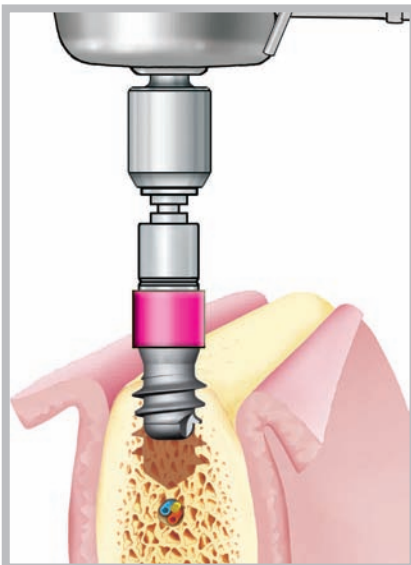
2.7 Remove the implant from the vial by exerting pressure on the vial's open side in order to detach the implant and make the vial fall down.

3) Placement of the implant

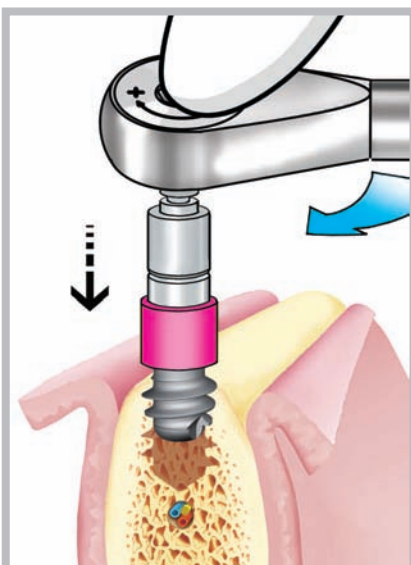


3.1 Initial seating of the implant in the implant site.

If the space for a direct connection between the implant carrier and the handpiece adapter is not enough, the extension Cat. 156-1002-00 may be used.



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

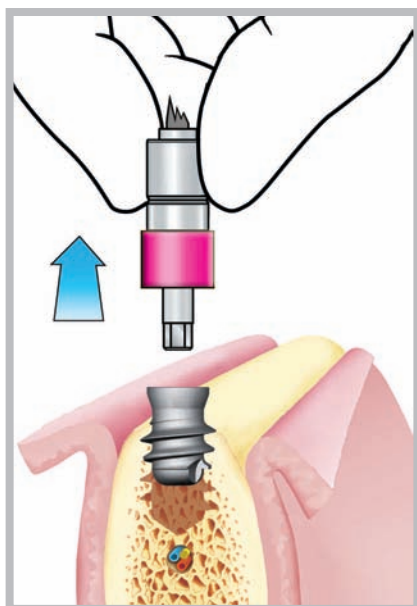


3.3 If the maximum torque value of 50 Ncm is not enough to complete the insertion of the implant, remove the handpiece adapter from the carrier and attach this to the ratchet Cat.156-1014-00.

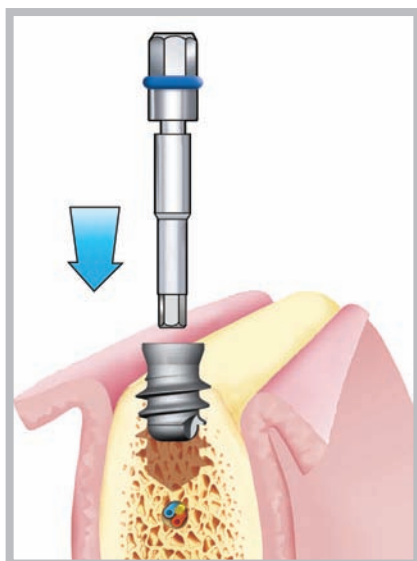
Be sure the instrument is directed in the long axis by lightly pressing the head of the instrument with a finger.



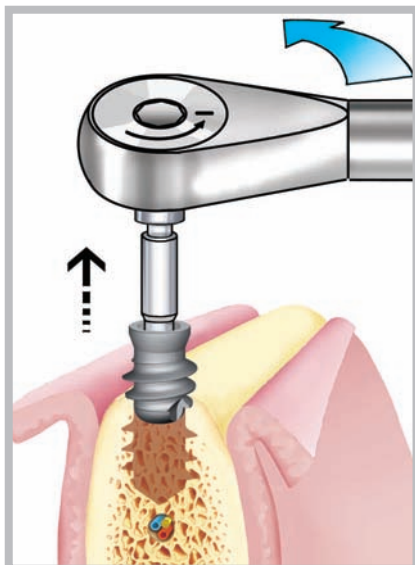
3.4 When using a ratchet, the forces exerted on the implant and on the correspondent peri-implant bone can become excessive. In this eventuality, should the value of 60 Ncm be overcome, a torque limiting device makes the carrier break above the connection with the implant; now the carrier can be removed.



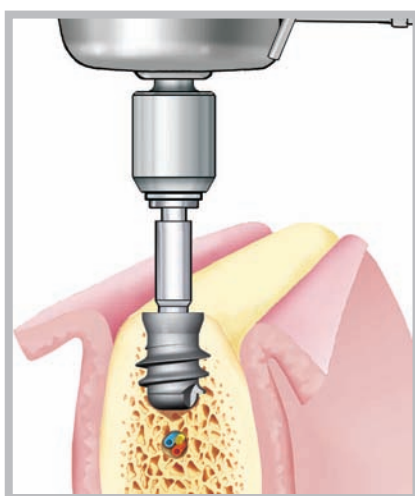
3.5 Removal of the fractured carrier.



3.6 Replace it with the implant driver Cat. 156-1013-00 available in the organizer Cat. 156-0019-00 withstanding a torque value applied of up to 140 Ncm and allowing the removal of the implant.

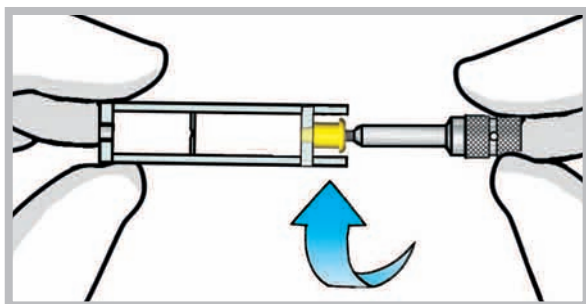


3.7 Attach the ratchet to the driver and remove the implant from the implant site. Tapping of the site with bone tap "B".



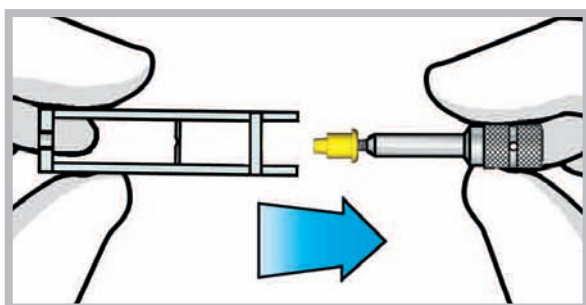
3.8 New seating of the implant by means of the implant micromotor with the driver attached to the handpiece adapter.

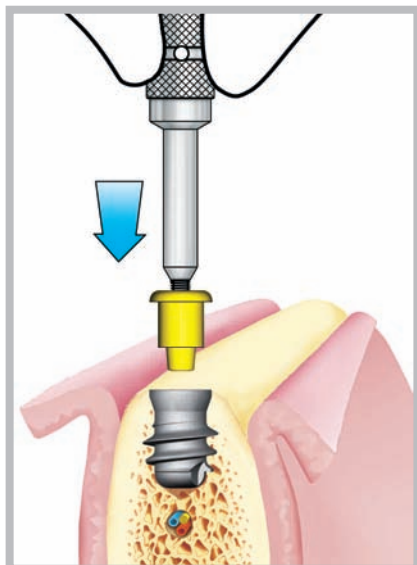
3.9 Internal rinsing and drying of the implant before placing the cover cap.



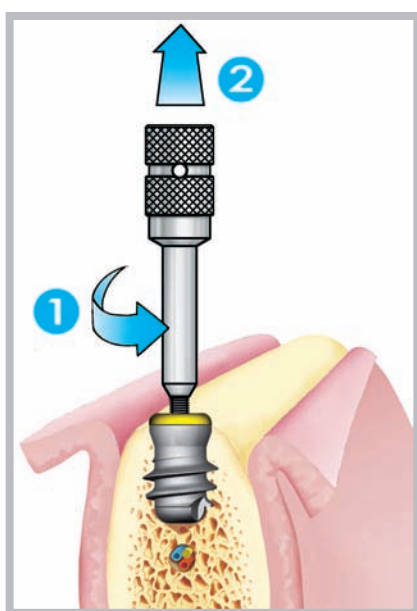
3.10 Take the vial that previously contained the implant. Screw the instrument for cover caps, Cat. 156-1003-00, on the head of the cover cap by giving only 2 turns.

The cap instrument presents a hole for the placement of a safety leash. Removal of the biopolymer cover cap from the special support by exerting a slight extraction force.

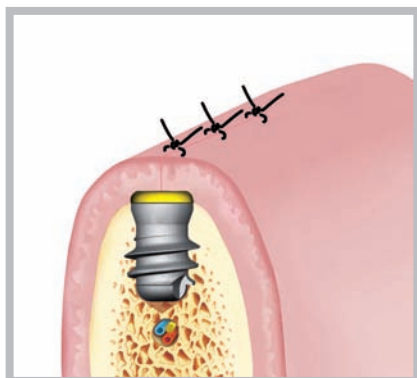




3.11 Positioning of the cover cap on the implant: push the cap home inside the implant.



3.12 Removal of the cap instrument by unscrewing counterclockwise. Push now the cap inside to its final position with a non sharp tool to perfectly seal the implant.



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


















For the next steps:

• SURGICAL PROCEDURE - SECOND STAGE • SOFT TISSUE CONDITIONING • PROSTHETIC PROCEDURE

refer to the Exacone Implant System procedures in our general catalogue for implant products, 2009 edition, which can be downloaded from our web site www.leone.it, taking into consideration that the inner connection's dimensions of the Exacone 6.5 short implant are exactly the same as those of a 4,1mm-diameter implant. (*Second surgical stage and Conditioning of soft tissues: pag. 48; Prosthetic Procedure: pag. 57*).

PRODUCT LABEL SYMBOLS

The label on the package of any medical device set on the market will show the symbols in compliance with the harmonized standards. The symbols marked with a single (*) are based on the EN 980 European Standard and on the 93/42EEC Directive. The symbols marked with double (**) have instead been performed by us.

manufacturer's trade name and address		manufacturer's catalogue code number and product description in different languages		bar code	
CE mark (made in compliance with 93/42EEC Directive on class IIA or IIB medical devices)		expiry date, if the product is perishable (year/month)	 (*) 2020/12	storage temperature	 (**)
lot number (indicated by LOT mark)		for professional use only	 (**)	for single use only	 (*)
keep dry	 (**)	this product contains Nickel-Chromium: possible allergic reactions	 (**)	keep away from sunlight	 (**)
CE mark (made in compliance with 93/42EEC Directive on class I medical devices)		see instructions for use	 (*)	gamma-ray sterilized	 (*)
titanium	 (**)	surgical steel	 (**)	this product contains Chromium: possible allergic reactions	 (**)
autoclavable at temperature indicated	 (**)	polyethylene	 (**)		

Information for distributors of dental implants: intended use, responsibility, surveillance

The 93/42EEC Directive on medical devices is the official reference that dictates the regulations for marketing medical devices. The directive provides indications for all the phases of existence for the device (from the project phase through the traceability system, and surveillance), and it identifies all the characters who have to comply with the directive itself, which includes not only the manufactures, but also the distributors, the buyers, and even the users.

As for the responsibilities of the single competence, Leone S.p.A. recommends to its direct clients, dental depots and exclusive dealers to follow and maintain the indications, warnings, and information for the univocal identification of the medical devices, as provided by the manufacturer on the labels, during all the marketing phases.

With specific regard to Class IIB implantable products, all dental depots and exclusive dealers of Leone S.p.A. are required to keep records of the distribution of medical devices as of traceability available for verification, in case of need to trace back a product or its user in a univocal way.

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