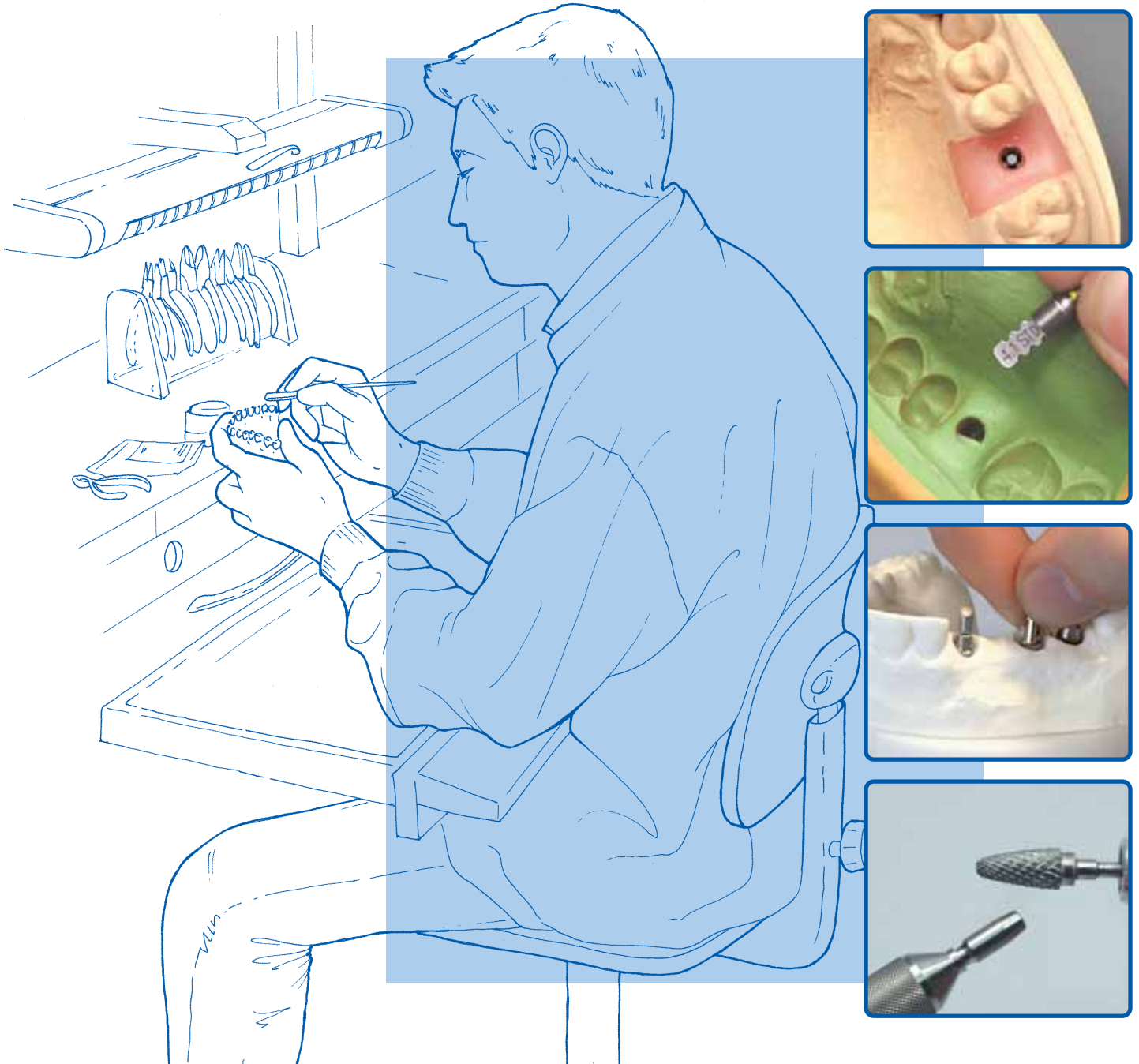


LEONE EXACONE™ IMPLANT SYSTEM



PROSTHETIC

PROCEDURE

DISCLAIMER

The Prosthetic 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 prosthetic 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.

PREMISE

The prosthetic procedure of the Leone EXACONE™ Implant System is similar to that used for the natural teeth.

For the preparation of the abutment and the realization of the definitive prosthesis on implants is possible to follow one "Direct Technique" or one "Indirect Technique."

The Direct Technique consists in the placement of the abutment directly in the mouth of the patient and in its preparation in situ. The impression taking and the preparation of the prosthesis follow the same method used for the abutments of natural teeth.

The Indirect Technique consists in the impression taking with the placement of the transfer inside the implants to reproduce on the cast the exact position. Both impression and transfer are sent to the dental laboratory where the abutments, the definitive prosthesis or the temporary prosthesis (if the clinician decides to favour a further conditioning of the soft tissues and for the application of a progressive load) are manufactured.

Caution: in case of corrections of notable problems of lack of parallelism among implants and the use of special abutments is required, the indirect technique is recommended.

For every implant platform (standard, large and slim) various types of abutments are available: cylinder and/or for the correction of possible lack of parallelism.

For standard platform straight or inclined anatomical abutments are available.

For the manufacture of removable prosthesis over implants, abutments for O-ring and bar overdenture are available.

For testing the most appropriate position to the specific case **two kits of test abutments** are available: one for the anatomical EXACONE™ 360° abutments, one for all the other Leone abutments.

Caution: the patient should be informed about the precautions for the period after installation of the implant in order to prevent complications and variations in the efficiency of the device: a good level of oral hygiene and periodical check-ups should be performed.

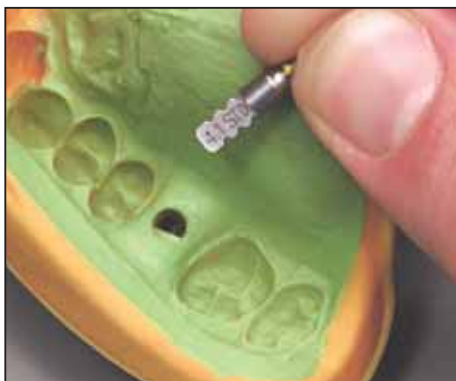
1) Indirect technique: impression taking



1.1 After having removed the healing cap, placement of the transfer that corresponds to the implant and to the selected platform. After having found the engagement in the internal hexagon exert a pressure on the transfer to get a perfect connection.



1.2 Impression taking either with single or with double impression technique. In case of double impression technique, after having taken the first impression, without the transfer, an adequate space is created in the material to take the second precision impression with a light body.



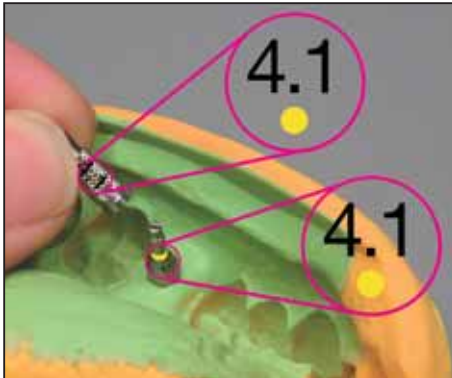
1.3 The transfer is kept in the impression due to the retentions. If this does not happen, thanks to the particular shape of the transfer, it will be quite easy to reposition it in the impression.



1.4 The impression is sent to the dental laboratory and the healing cap is repositioned on the implant following the previous described procedures.

2) Indirect technique: preparation of the dental cast

2.1 Check for correct position of the transfer on the impression or, if necessary, reposition the transfer.



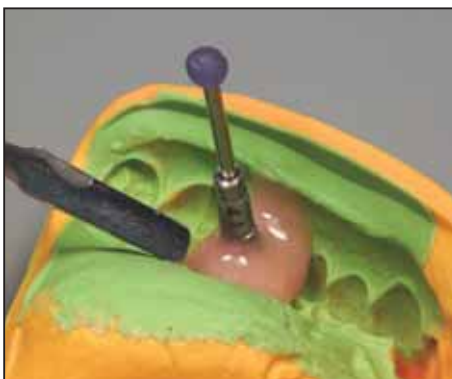
2.2 Verify the correspondence of the suitable dimensions and colour code on the surface of both analog and transfer. For the realization of dental casts with silicon gums, the use of the long analog is recommended. Placement of the analog on the transfer through the positioning hexagon which is present on the transfer. Exert a slight pressure on the analog until its complete placement.



2.3 **Warning:** the analog must be seated completely in order to avoid errors in the manufacturing of the dental cast.



2.4 Placement of the pin on the analog.
The connection among the two elements happens through a conic interference with no need of further fixing methods.



2.5 Placement of a small ball of wax on the extremity of the pin. The position of the ball will indicate the presence of the pin in case the pin would not come out of the dental cast. During this phase, non-rigid resin material can be used on the cast to mimic the presence of soft tissues. Pouring of the material that simulates the gingiva around the area of the analog.



2.6 The plaster is poured making sure that the position of the pin is not modified.



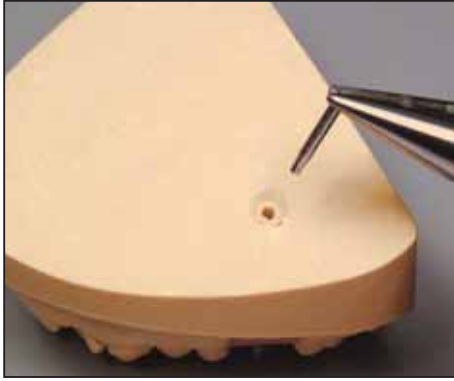
2.7 After curing of the plaster, the cast is removed from the impression carefully and it is checked for imperfections. Due to its retentive design, the transfer is kept in the impression.



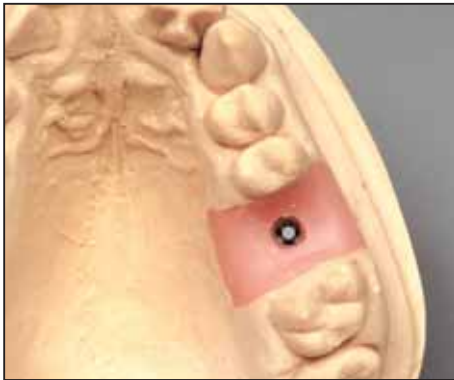
2.8 The cast is trimmed until the wax over the pin gets exposed.



2.9 The opening on the plaster of the cast is widened when the gap created by the wax ball is not sufficient for the extraction of the pin.



2.10 The pin is extracted from the cast with a laboratory plier. In this way, a posterior access canal to the analog is created.

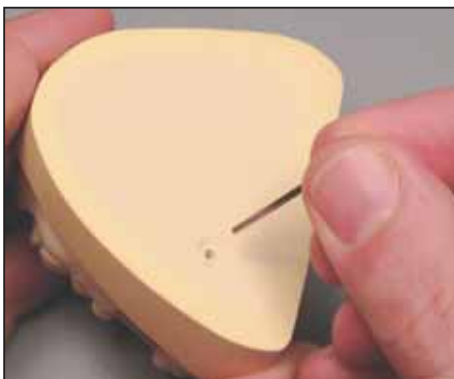


2.11 Final result: cast with analog seated in the correct position with regard to implant position in patient's mouth.

3) Indirect technique: preparation of the abutment



3.1 With the use of test abutments (pages 12 and 20) select the ideal abutment and seat it on the analog with the exertion of impulsive force (beat on the top of the analog with a small hammer). Particular care must be taken in finding the engagement in the internal hexagon, for the control of the dimensions and planning of subsequent modifications.



3.2 Placement of the specific rod for removal of the abutment in the access canal created previously on the base of the cast.



3.3 Percussion with a small hammer and extraction of the abutment from the analog.



3.4 Placement of the abutment on the specific handle for holding abutment. Particular care must be taken in finding the engagement in the internal hexagon. The handle facilitates the reduction of the abutment and prevents any damages to the abutment. It also avoids problems due to overheating and unstable grips.



3.5 First phase of the reduction of the abutment seated on the handle. The abutments of the LEONE EXACONE™ Implant System allow an easy preparation both in the laboratory and in the patient's mouth, due to the particular quality of the titanium utilized and to their design (solid abutments). Separation disks and cross cut tungsten carbide burs are particularly indicated for this type of preparation.



3.6 Removal of the abutment from the handle. The handle has a special push-button that allows a simple and rapid ejection of the abutment.

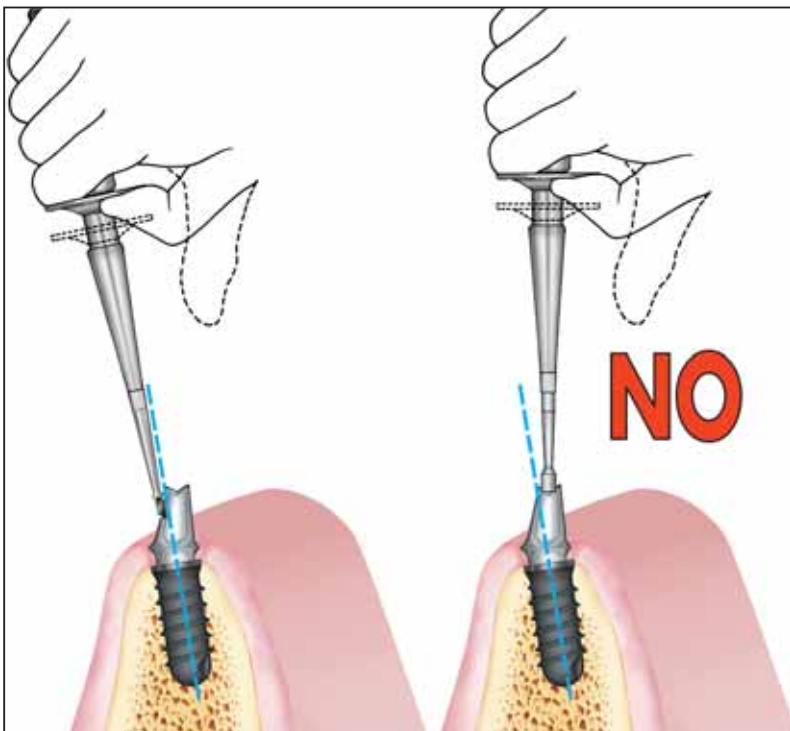


3.7 Placement of the semi-finished abutment in the analog and application of an impulsive force. If necessary, the abutment can be finished on the cast with a milling parallelometer.



3.8 Placement of the specific rod for removal of the abutment in the access canal created previously on the base of the cast. Percussion with a small hammer and extraction of the abutment from the analog.

Warning: in case of abutments reduced with a particularly accentuated angulation, create a notch parallel to the main axis of the cone. The rod or the specific beater will be placed in the notch for a correct percussion of the abutment on the implant. The anatomical abutments already show the notch parallel to the main axis. Percussion on the anatomical and offset abutments, on which a notch has been created, must be performed with the special seating tip for abutments Cat. 156-1008-06, watching out to tilt the instrument along the implant axis. On the contrary, the seating tip might not find the correct support on the notch and slip sideways.

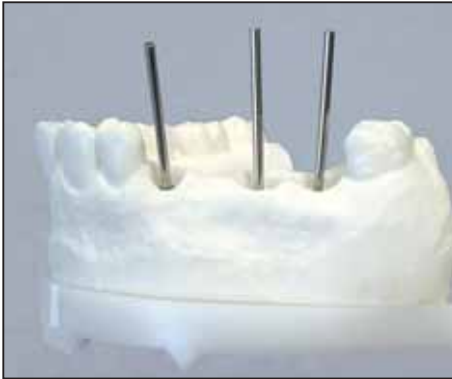


3.9 Waxing, casting and try-in of the coping or of the framework on the abutments that will be marked with numbers indicating their position and with a sign on the vestibular side. Manufacture of a temporary prosthesis. Sending of abutments and copings or frameworks and temporary prosthesis to the dental office.



4) Indirect technique:
selection, usage and positioning of anatomical abutments

EXACONE™ 360°



4.1 Highlight the different implant inclination by seating the pins (included in the package) on the analogs or on the related test abutments.



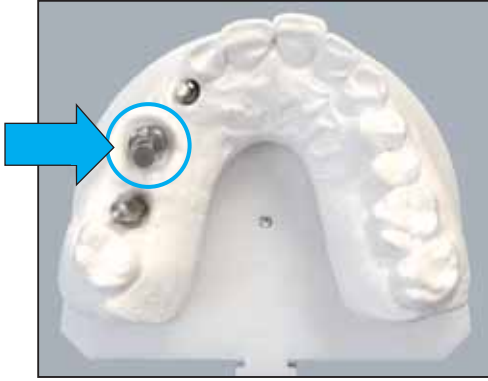
4.2 Selection of the most appropriate test abutment **EXACONE™ 360°** from the kit (Cat. 160-0001-01). It is now possible to order the correct selected abutment.



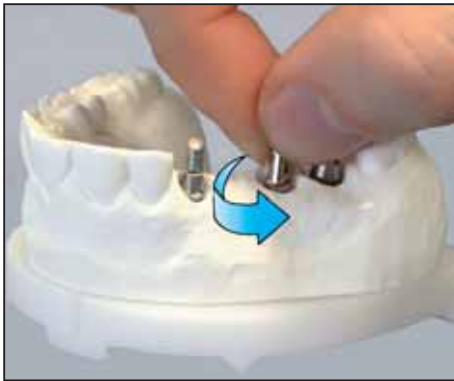
4.3 The apical hexagon is only seated but not permanently connected to the anatomical abutment **EXACONE™ 360°**: this allows a free positioning to 360° on the model. When supplied, the conical locking-taper connection between the hexagon and the abutment is not activated, therefore the hexagon can rotate on the abutment.



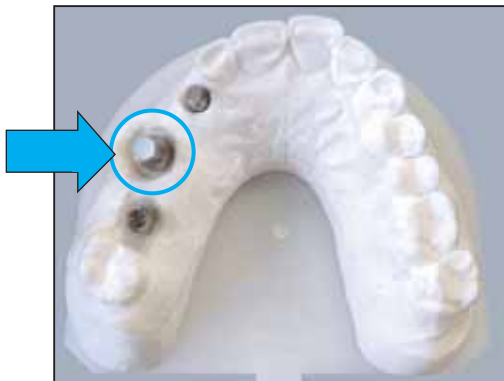
4.4 Slightly press the abutment on the corresponding analog on the model.



4.5 The angular position of the hexagon is casual and accordingly the abutment emergence.



4.6 Take the anatomical abutment EXACONE™ 360° and rotate it to its correct angular position. Eventually use an universal plier.



4.7 In this way the best parallelism among abutments has been set and the placement axis has been selected.



4.8 Fix the position through an impulsive force on abutments.



4.9 Placement of the special pin for the abutment removal into the access channel on the bottom of the model.



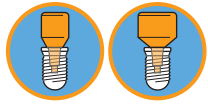
4.10 Application of an impulsive force on the pin. The hexagon is permanently fixed to the abutment and at the same time the abutment is being removed from the analog.



4.11 Extraction of the abutment from the model. The hexagon is now fixed in the pre-defined position and it is more favourable to the prosthetic restoration. Finishing of the abutment, if necessary, and manufacturing of the framework making reference to points 3.4-3.9.

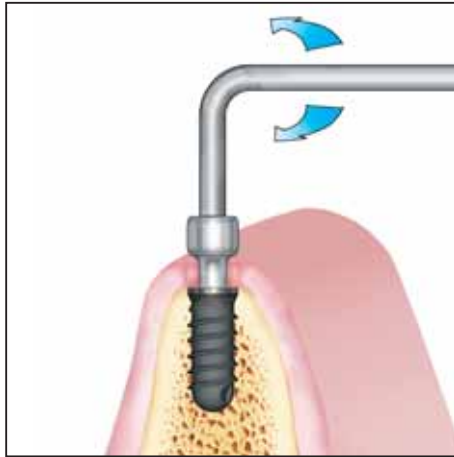


4.12 Once activated the self-locking conical connection ensures the stability of the hexagon and the positioning of the abutment in the mouth is only one-way. For the final positioning of the abutment, follow the general instructions indicated at points 5.1-5.6. In case of choice of an anatomical abutment **EXACONE™ 360°** either angled at 15° or 25°, the activation of the connection must be performed on the special indent with the flat point Cat. 156-1008-06.



5) Indirect technique: final positioning for standard and large platform

The prosthetic technique of EXACONE™ Implant System is similar to the one always used on natural teeth. The dental praxis receives the abutments, the cap or the metal framework from the laboratory.



5.1 Removal of the healing cap with the specific hex head extractor Cat. 156-1006-00. The extractor, which presents 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 indifferently, in order to extract the healing cap. The removal of the cap of the implant is completed with the aid of a tweezer. Accurate rinsing and drying of the inside of the implant.

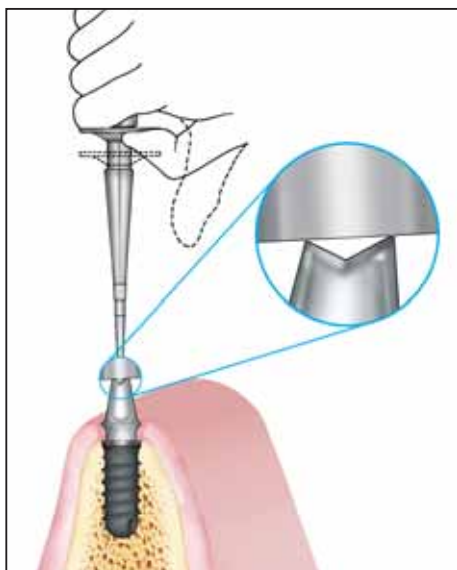


5.2 For the abutment try-in, the abutments are placed inside the implants paying attention to the corresponding numbers. The hexagonal engagement is found and a light manual pressure is exerted on the abutments. By doing so, the abutments will be sufficiently retained inside the implants and, if necessary, at the end of the try-in procedure, the abutments can be easily removed either manually or with a plier.



5.3 Try-in of the coping or of the framework on the abutments. Once the perfect adaptation between the metal structure and the abutments has been checked, the copings or the framework are sent to the laboratory for the completion of the manufacturing process. [1]

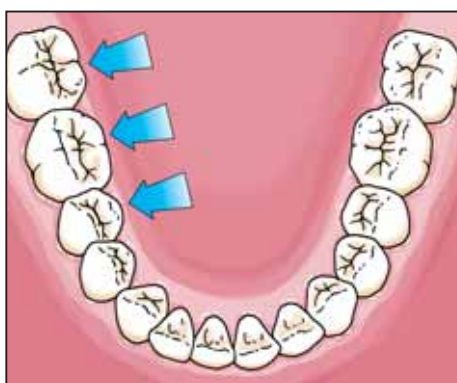
[1] In the event of an imperfect adaptation of the framework, it may be cut and repositioned on the abutments if suggested by the clinician. The adaptation of the framework is checked in the mouth of the patient and the framework is fixed with self-curing resin. Once the final set of the self-curing resin has occurred, an impression is taken with the framework still in place. The framework kept in the impression is sent to the laboratory for final soldering - the technique is the same as the one on natural teeth.



5.4 The clinician may decide for the final placement of abutments inside the implants by placing a temporary prosthesis. In this case, the placement of the abutments is performed by applying an impulsive force along the longitudinal axis of the implants with the special abutment small hammer. In order to get a permanent connection, 2 consecutive percussions are advisable.



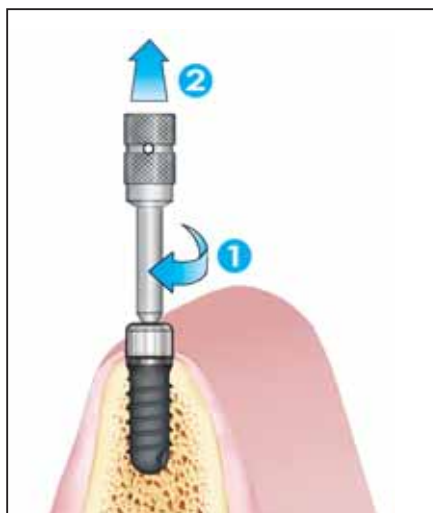
5.5 Application of a temporary prosthesis may promote further conditioning of the soft tissues and application of a progressive loading. As an alternative, the abutments can be removed with a plier and the healing caps are repositioned. Once the final prosthesis is ready, the healing caps are removed, the abutments are definitively seated and the prosthesis is applied.



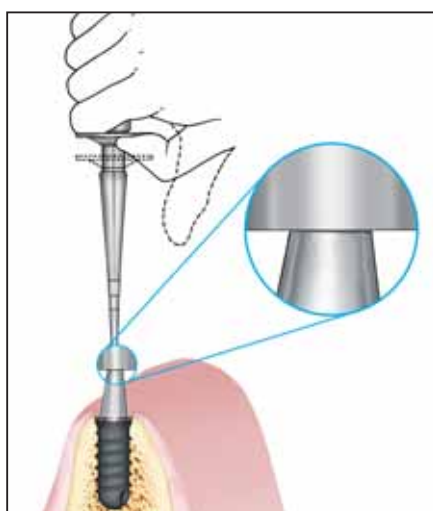
5.6 Once the prosthodontist has decided to apply the final manufacture, the temporary prosthesis is removed. After final touches and polishing, the final prosthesis is positioned and cemented.



6) Indirect technique: final positioning for slim platform



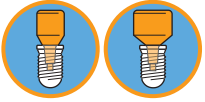
6.1 Removal of the healing cap with the special instrument for cover caps Cat. 156-1003-00. The instrument for caps has to be screwed in the head of the healing cap in order to exert enough pull to remove the cap.



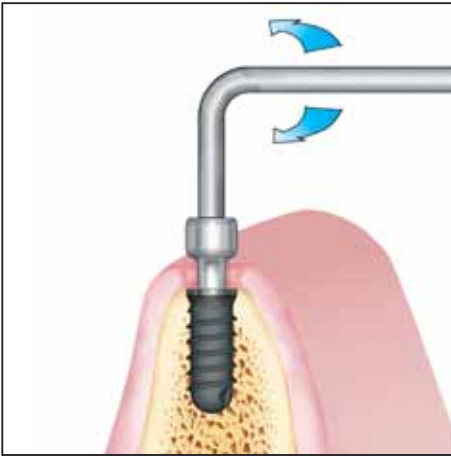
6.2 Final placement of the abutment in the implant through the application of an impulsive force along the longitudinal axis of the implant with the special hammer. To get a permanent connection, 2 consecutive percussions are advisable.



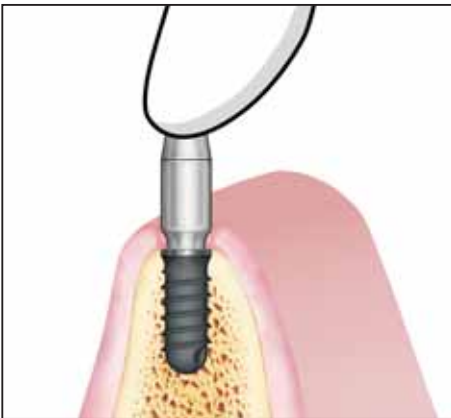
6.3 Cementation of the crown with closing on the neck of the implant.



7) Direct technique: positioning and preparation of the abutment, impression taking for standard and large platform



7.1 Removal of the healing cap, rinsing and drying of the internal part of the implant.



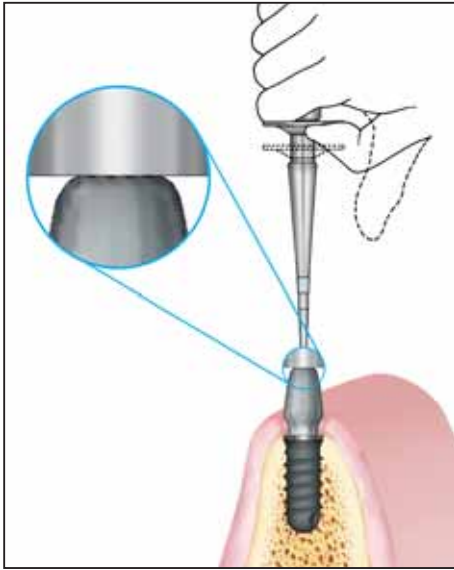
7.2 Selection of the most appropriate abutment from the test kit (Cat. 160-0001-02). Test of the abutment in mouth of the patient. Placement of the abutment in the implant taking particular care to find the exact engagement in the internal hexagon. Following pressure to get a retention of the abutment inside the implant. Highlighting of possible parts to be trimmed. Hand removal of the abutment or with the help of a plier.



7.3 Eventual rough shaping of the abutment, especially in height, with the aid of the special handle for abutment.



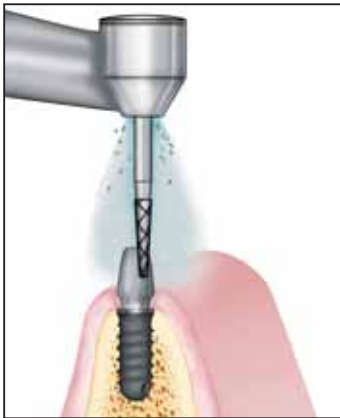
7.4 When rough shaping is finished, placement of the abutment in the implant taking particular care to find the engagement in the internal hexagon.



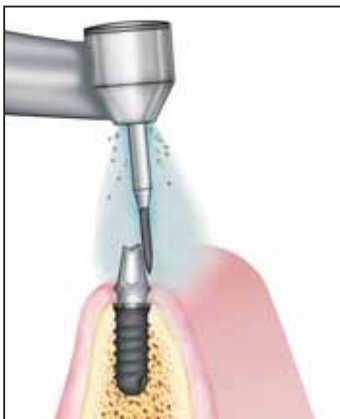
7.5 Percussion of the abutment with the specific hammer on the longitudinal axis of the implant. To get a permanent connection, 2 consecutive percussions are advisable.

7.6 Milling of the abutment directly in the patient's mouth while **thoroughly flushing with water**.

The abutments of the LEONE EXACONE™ Implant System allow an easy preparation both in the laboratory and in the patient's mouth thanks to the low thermic conductivity coefficient of the titanium with which they are manufactured.



7.6a For important cuts in height and rough shaping, the use of a cross cut tungsten carbide bur Cat. 153-1221-02 or Cat. 153-1235-02 (included in the specific organizer) is recommended. We advise to prepare the abutment as a chamfer.

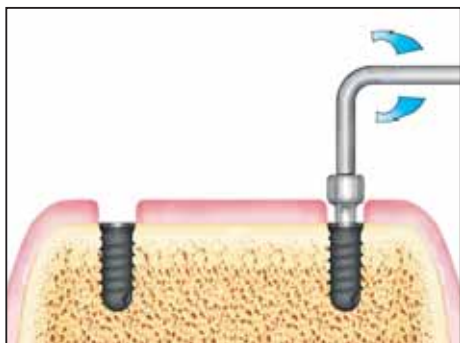


7.6b For the final finishing use a coarse-cut diamond bur Cat. 153-1610-01 or Cat. 153-1810-01 included in the specific organizer.

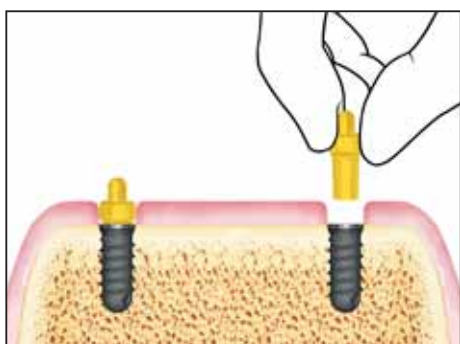
7.7 Impression taking with classical technique as on the natural teeth and dispatch of the same to the dental laboratory for the preparation of the prosthesis. The application of a temporary prosthesis is advisable to get a conditioning of the soft tissues.



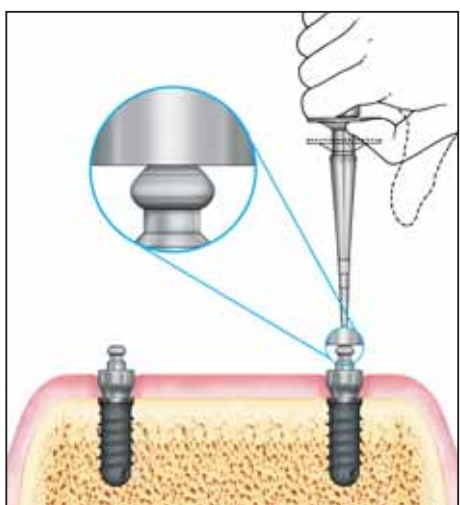
8) Overdenture O-ring



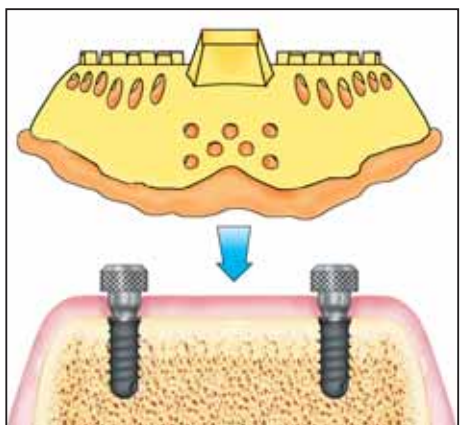
8.1 Once the soft tissues have healed over, the healing caps are removed.



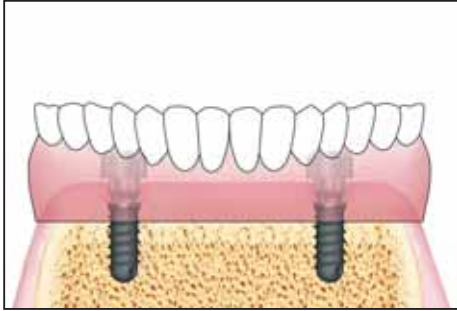
8.2 Selection of abutments for O-ring overdenture from the test abutment kit Cat. 160-0001-02 according to the height of gingival tissues available and inclination of implants. The abutment must surmount the gingiva of at least 1 mm to avoid the spacers to compress the soft tissues.



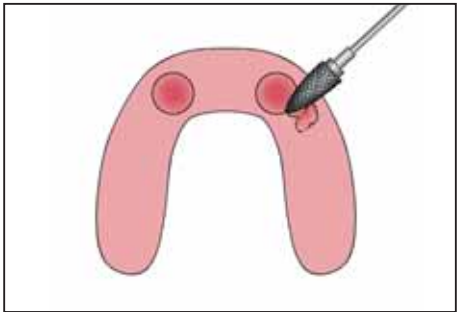
8.3 After rinsing and drying the internal part of the implant accurately, the abutment of the O-ring overdenture is seated on the implants with the application of an impulsive force (percussion with the specific hammer) along the longitudinal axis. To get a permanent connection, 2 consecutive percussions are advisable.



8.4 The spacers for O-ring overdenture are placed on the abutments. Impression is taken and sent to the laboratory. In this way, the manufacturing of the prosthesis can occur with an adequate space in relation to the spacers. The spacers are removed and the temporary prosthesis is adapted.

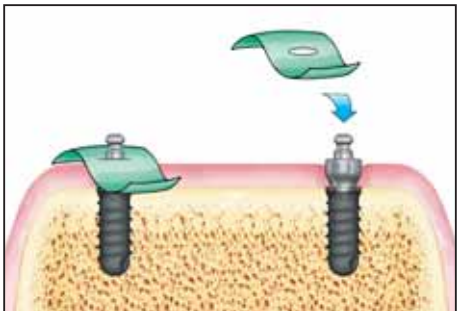


8.5 The final prosthesis is checked, particularly in relation to the space left for the seating of the spacers.

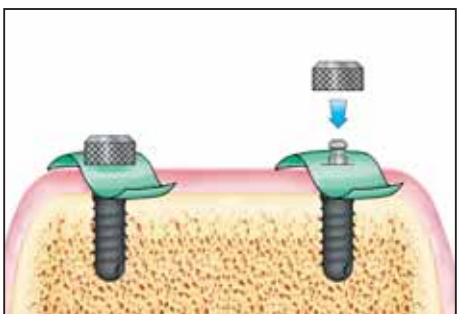


8.6 The overdenture may be trimmed and carved in correspondence of the seatings for the spacers in order to obtain a perfect mucosal adaptation of the prosthesis without friction on the spacers for O-ring overdenture.

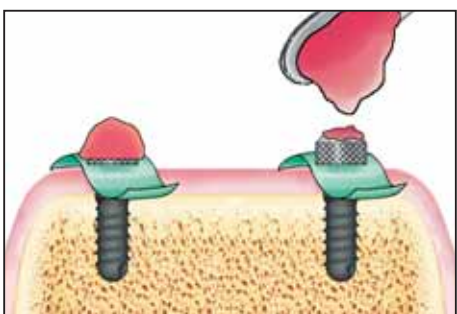
N.B. It is recommended to deliver the final overdenture without spacers to the patient so that the tissues can be adequately conditioned and possible impingements can be corrected. The situation should be kept stable for an adequate period that will be evaluated by the clinician.



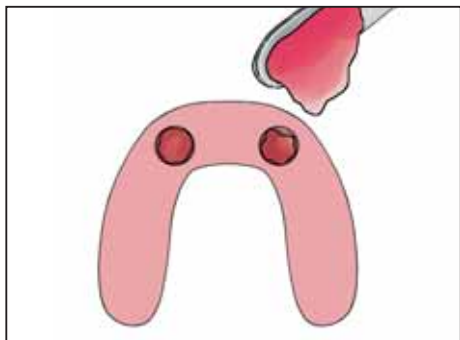
8.7 The prosthesis is delivered to the patient. When the conditions are stable, a squared portion of rubber dam is positioned in correspondence of each abutment, so to avoid a direct contact between the soft tissues and the acrylic.



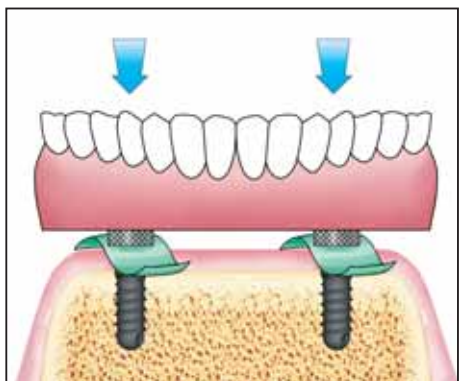
8.8 The spacers are seated on the abutments for O-ring overdenture.



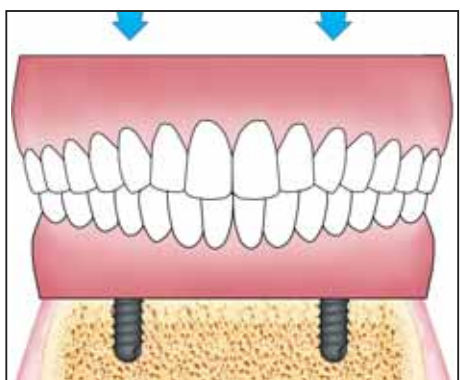
8.9 The acrylic is poured on the spacers.



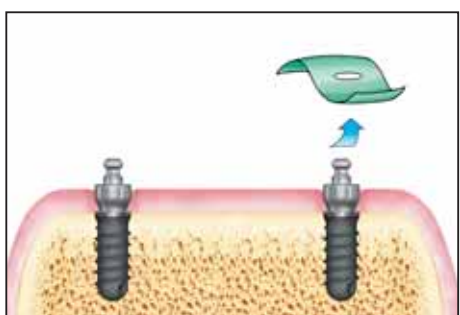
8.10 The spacer seatings in the overdenture are filled with acrylic as well.



8.11 The prosthesis is seated on the abutments in the patient's mouth.



8.12 The patient closes the mouth with adequate occlusal contacts.

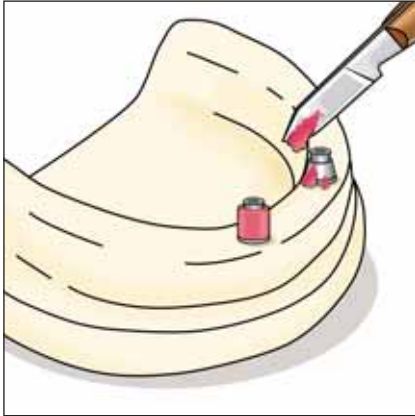


8.13 When the polymerization process of the acrylic is over, the prosthesis is removed from the patient's mouth. The spacers, due to their highly retentive surface, are kept in the prosthesis. The rubber dams are removed from the abutments.



8.14 The excess of acrylic is removed until the lower border of the spacers becomes apparent. The portions of acrylic that could create impingement problems close to the implants are removed as well. The overdenture is polished. The prosthesis is delivered to the patient.

9) Bar-clip Overdenture

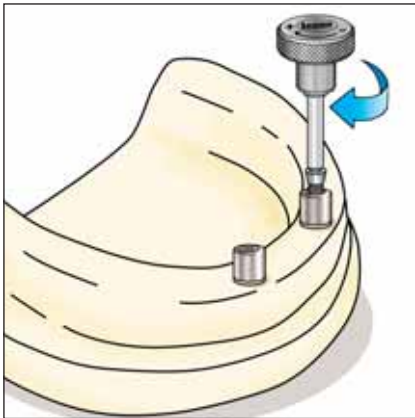


9.1 After the healing of soft tissues, take the impression with the conventional indirect technique and pour the plaster.

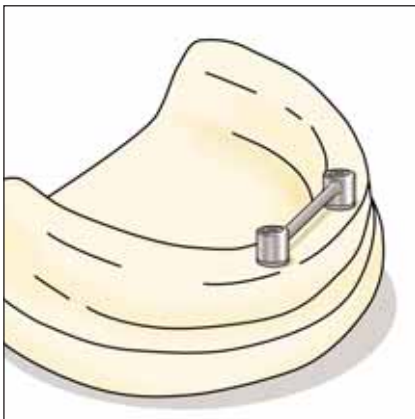
Abutments for bar-clip overdenture have a tapered head.

Selection of bar clip overdenture from the test abutment kit Cat. 160-0001-02 according to the height of gingival tissues available and inclination of implants.

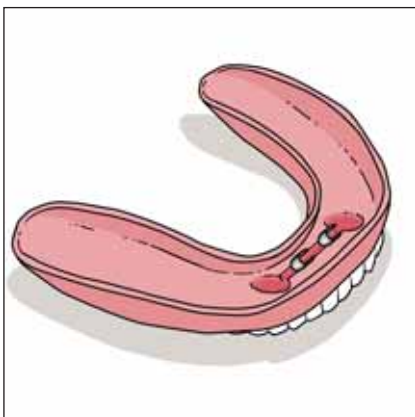
Pre-fabricated copings made of golden alloy *Ceramicor*® (page 16) can be used to make the bar; as an alternative new copings can be cast in the dental laboratory. In this case it is necessary to model them directly on the abutment with the connecting screw being screwed in but not tightened.



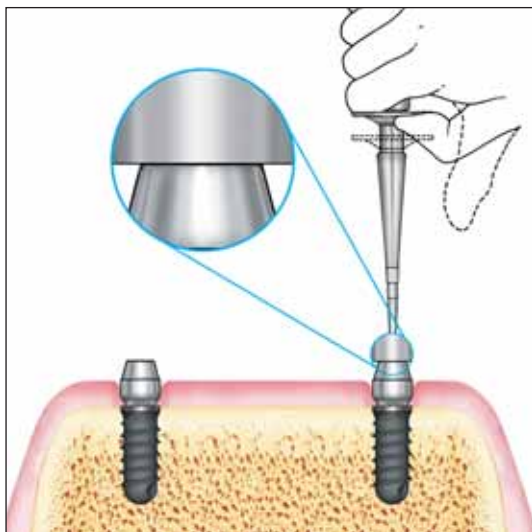
9.2 Connect the copings to the abutments with the connecting screws. Screw them with the hand screwdriver connected to the proper adapter Cat. 126-0002-00.



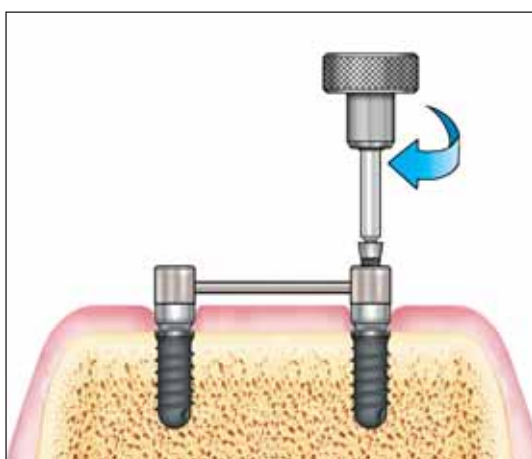
9.3 Fix the tailored golden alloy bar segments to the copings by brazing or reproducing them with cast procedures (refer to page 79 for the suggested alloys). Polish the bar.



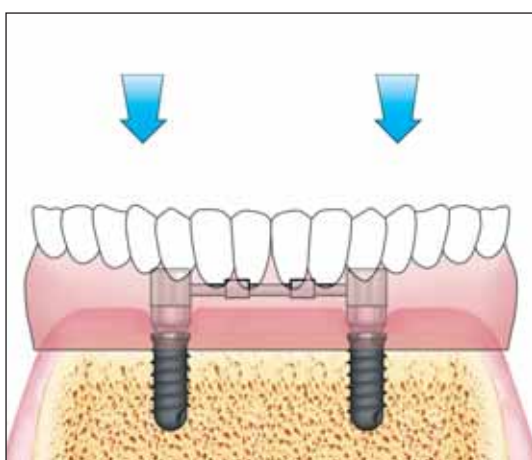
9.4 Make a new denture with a proper seating for the bar or adapt the pre-existent one. Seat the metal riders, onto the bar and fix them into the prosthesis. Return the prosthesis to the dentist.



9.5 Connect permanently the abutments to the fixtures, by seating and tapping them with the specific beater. In order to have a permanent connection two consecutive taps are recommended.



9.6 Place the bar and screw the connecting screws into the abutments with the hand screwdriver connected to the adapter Cat. 126-0002-00.



9.7 Clasp the prosthesis to the bar with the riders.

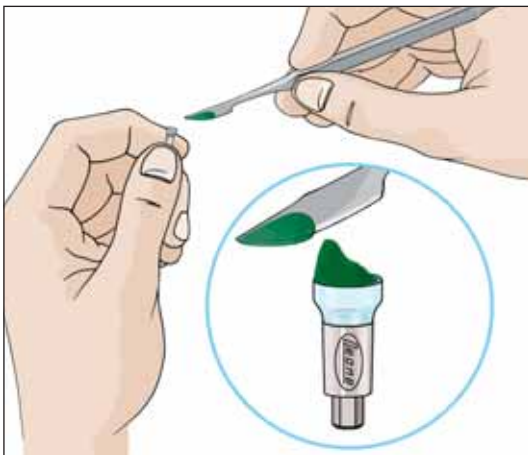
10) Cast-on gold abutments - Laboratory Procedure



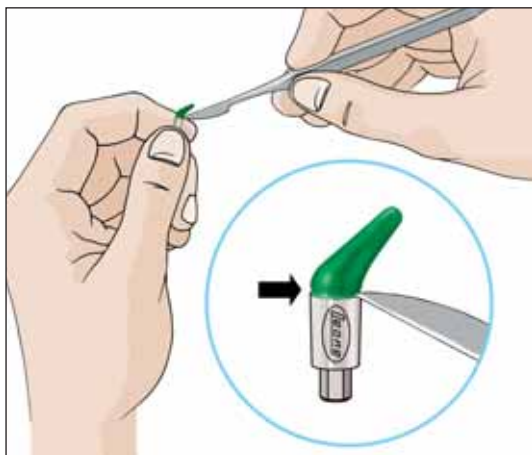
10.1 Place the chosen burn-out coping on the gold abutment, thanks to its central pin.



10.2 Fix the coping to the abutment with cyanoacrylate.



10.3 If necessary, the coping may be adapted with a scalpel; make the modelling with wax or some other burn-out material. Since the gold abutment is solid while the investment material expands in order to compensate the shrinkage of the alloy, an unwanted contour could form, preventing from a proper connection. To avoid this problem the coping is slightly thinner where it gets in touch with the gold abutment.



10.3a If the coping is not used, a small depression around the interface with the gold abutment is recommended.

Do not cover the upper cylindrical part of the gold abutment with wax, because, at the end of the process, it could prevent the abutment from a proper placement into the implant.



10.4 Finish the wax modelling with a spatula.

10.5 After the modelling, thoroughly clean the abutment with alcohol. Do not use wetting agents.

10.6 Cast-on the abutment in the conventional way. When selecting the casting alloy, ensure that is compatible with the high-fusing *Ceramicor*® alloy: the melting range of the casting alloy must not exceed a liquidus temperature of 1350°C (2462°F). Suitable dental casting alloys are: high noble alloys, precious metal alloys with a minimum content of gold and platinum group metals of 25%, palladium based alloys with a minimum content of palladium of 50%.

Caution: *Ceramicor*® alloy cannot be cast-on with CrCo and NiCr alloys.

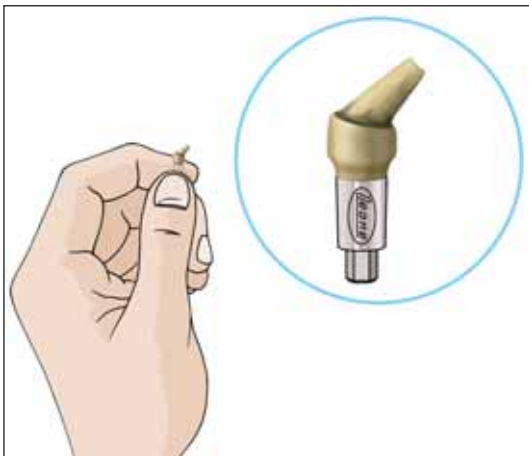
The use of the casting alloys indicated above and of investment materials matching to the alloy used is strictly recommended. Follow the investment material manufacturer's instructions on the mixing ratio and the pre-heating times. The use of investment materials for rapid heating methods (speed investment materials) is not recommended.

10.7 Once the mold has slowly cooled to room temperature, carefully remove the investment material from the cast abutment, taking care not to damage the self-locking conical part. High content of palladium alloys, like *Ceramicor*®, are brittle at high temperatures: carry out the deinvestment after the cylinder has completely cooled.

10.8 Devest with ultrasound, water jet, pickling acid or glass fiber brush. The use of sand-blasting for deinvesting is not recommended, since it could damage the self-locking conical part.

10.9 Trim the sprues and finish the cast part of the abutment.

If some casting beads are present on the self-locking conical part, they cannot be removed without damaging the conical part itself: never use such abutment.



10.10 Polish the cast part of the abutment, without touching the self-locking conical part. In this operation and whenever necessary during the finishing, the use of the handle for abutments is recommended. It ensures a firm grip and does not damage the connection part.