SURGICAL AND PROSTHETIC PROCEDURE

FOR MONOIMPLANTS FOR O-RING OVERDENTURE

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

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DISCLAIMER

The Surgical and Prosthetic Procedures related to the use of the Leone products for Monoimplants for O-ring overdenture described in the following pages are intended for Professionals experienced in dental implant techniques.
In case of lack of basic notions, we suggest to attend specific courses in order to reach a high level of knowledge and practice in the use of implants. The instructions for use of the products described below represent a sort of standard instructions that have to be adjusted to the individual needs and to the particular situations that may occur on the basis of the manual ability, the experience and diagnosis effected 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 Monoimplants for O-ring overdenture shall completely be reverted to the clinician. The surgical procedure hereunder described is merely indicative as any single treatment case is assigned to the experience of the operator. As every medical operator well knows, a correct procedure and a perfect manufacture of the prosthesis may sometimes be followed by not satisfactory results owing to particular situations not imputable to responsibility of the dental operator or the manufacturer.

TREATMENT PLANNING

Indications
The Leone Monoimplant for O-ring overdenture therapy is indicated in the treatment of the TOTAL LOWER EDENTULISM.

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

PREOPERATIVE EXAMS

Before starting the surgical intervention, the patients have to be subjected to a series of exams; any single case has to be evaluated by 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, priorities, degree of compliance and motivation.
Anamnesis can help in evaluating the need for extra exams in addition to the routine ones (when the presence of pathologies that were not reported by the patient is suspected) and when particular situations drive to deem a complete medico-surgical exam may be necessary.

Objective exam
It consists of:
- inspection of the periodontal tissues, of the oral mucosa and of the teeth along with an initial evaluation of the occlusal relationships (skeletal Class, characteristics of the opposing arch and related potential problems, type of occlusion, interarch distance), of the presence of parafunctions, of the degree of oral hygiene, of the aesthetic conditions, of the morphology of the edentulous crest and the space available for the replacement of the prosthesis.
- palpation of the soft tissues and implant sites for a preliminary evaluation of the bone morphology and thickness.
- a complete periodontal probing for the appraisal of the absence of both gingivitis and pockets.

Radiographic exams
PANORAMIC RADIOGRAPH: frequently, this radiograph allows an appraisal of the bone height and the relationships between implant site and adjacent structures, such as mandibular canal, etc.
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 apico-coronal availability of bone.
LATERAL CEPHALOGRAM: it is useful for the determination of the mandibular symphysis.
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
When necessary, in cases where a pathology is suspected on the basis of anamnesis or clinical records.

MONOIMPLANT SELECTION

The dimensions (implant length and transmucosal neck height) of the monoimplants to be seated are determined by the following factors:
1. amount of bone available
2. characteristics of the implant site
3. thickness of the soft tissues in the areas involved.
Further and particular individual situations must be evaluated by the Dentist or the Dental Surgeon.
Do not place monoimplants in the upper arch.

A template is available that shows all Leone monoimplants GH3 in actual dimensions, with dimensions increased by 10% and increased by 25%, to match possible distortions created by the X-ray unit.

To simplify the surgical operation, an organizer for monoimplants is available to sterilize and hold on the surgical field the necessary instruments.

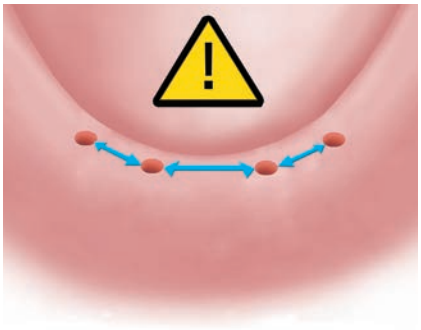
LEONE SURGICAL INSTRUMENTS ARE SUPPLIED NON-STERILE: CLEANING, DISINFECTION AND STERILIZATION AFTER REMOVAL FROM THE PACKAGE AND PRIOR TO EACH FURTHER USE ARE REQUIRED. CONSULT THE *"Guidelines for cleaning, disinfection and sterilization of reusable XCN® Leone instruments"* AVAILABLE FOR DOWNLOAD AT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

Interactions between dental implant and medical imaging techniques
Titanium dental implants hardly are not magnetic and are not heated during a Magnetic Resonance Imaging (MRI) and the artifacts on the bioimage are usually attributable to the implant-prosthetic device. For further details please refer to the document "Interactions between Leone orthodontic and implantology devices and medical imaging techniques" available for download at **www.leone.it** in the section **Services/Quality.**

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

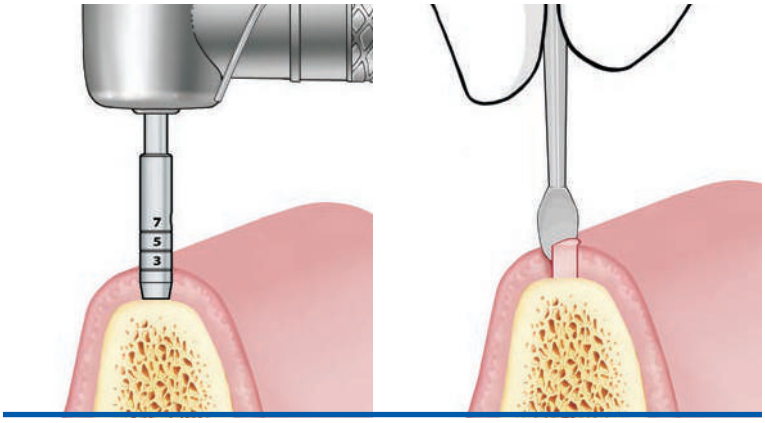
1. PREPARATION OF THE IMPLANT SITE

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.

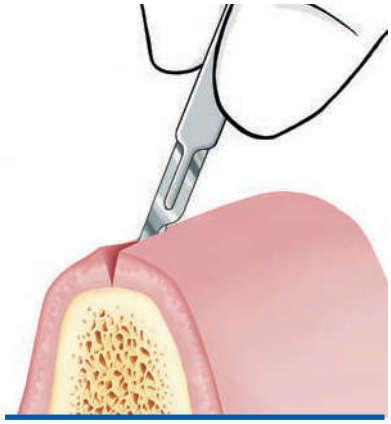


minimum 6 mm

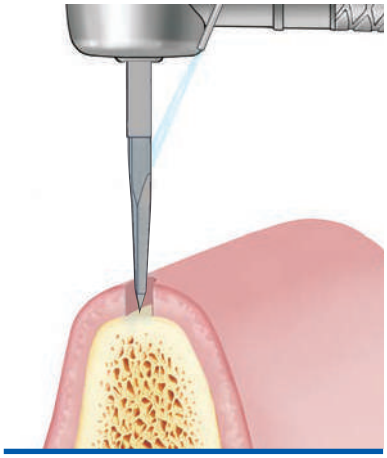
1.1 After adequate treatment planning, clearly mark the locations where the monoimplants must be inserted with a marker pen or a surgical template.
The Leone monoimplants must only be inserted in the mandible, at the level of the mandibular symphysis, located in the area between the two foramina.
The number of monoimplants required to adequately support a removable prosthesis is 4. The minimum required space between each implant and the next is 6 mm. This will allow the correct positioning of the micro housings.
The inclination of every single implant shall not exceed 8° to the axis of parallelism.
Make sure that the prosthesis is tissue borne and only implant retained. Avoid any implant-prosthetic load on the monoimplants since they are strictly a retentive element.



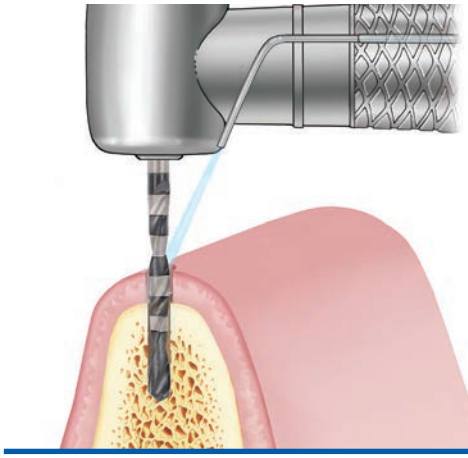
1.2a Flapless procedure
Punch the mucosa with the use of the special Ø 2,7 mucotome for handpiece. Use the mucotome with the micromotor set to a low speed (approx. 40 rpm). Use until bony tissue is met. On the mucotome there are three reference lines, at the heights of 3-5-7 mm starting from the crestal bone and acting as a reference for the measurement of the gingival height.
Remove the mucosa punch and the tissue plug by using a small periosteal elevator.



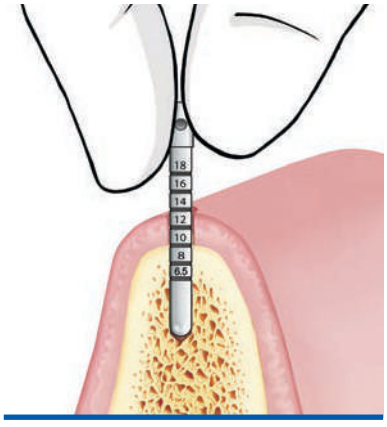
1.2b Flapping procedure
In case there are uncertainties on the condition of the crestal bone or the quantity of bone available, the use of a gingival flap procedure is advisable. Start with a scalpel incision of the soft tissues, then open the gingival flap for a clearer vision of the crestal bone: the osteotomy can now be performed.



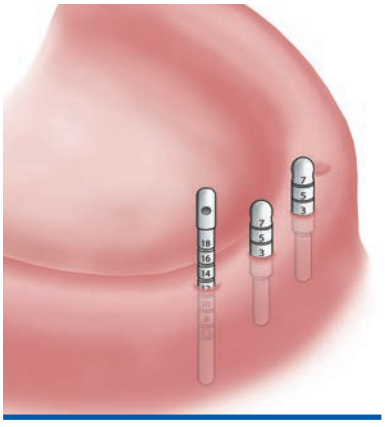
1.3 Once the gingival tunnel has been performed, use the round bur or lance drill to mark the cortical bone for the pilot drill.



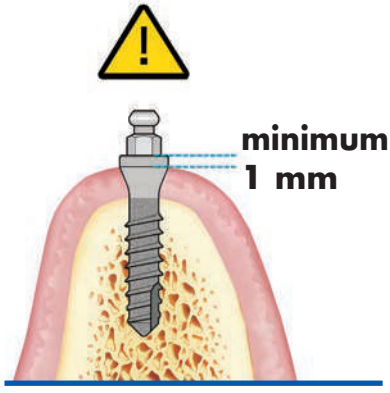
1.4 Insert the long pilot drill Ø 2,2 mm into the hole and drill the bone until the length of the desired monoimplant has been reached (max. speed of 800 rpm with adequate irrigation). The drilling depth is clearly indicated by black DLC (Diamond-Like Carbon) coated depth marks on the drill. Pay attention to the length of the monoimplant, to which the height of the soft tissues has to be added.



1.5 Insert the depth gauge into the newly created implant site to check its depth, considering also the height of soft tissues.



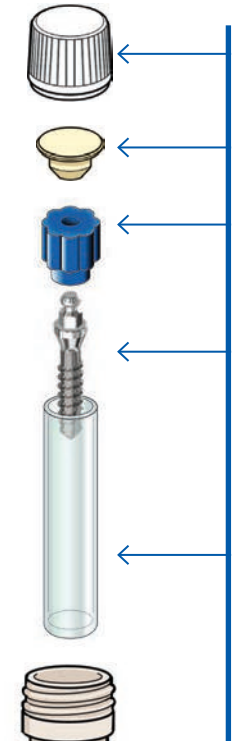
1.6 Repeat points 1.2 - 1.5 for the other three monoimplants, ensuring the maximum degree of parallelism among the surgical sites. Check the parallelism of the monoimplants using the measuring pins for gingival height and the depth gauge.
The measuring pins may also be used at any other time to check soft tissue thickness.



1.7 Choose the transmucosal neck height of the monoimplant.
The head of the monoimplant must protrude from the gingiva by at least 1 mm to avoid a possible impingement of the micro housing on the patient's soft tissues.

2. MONOIMPLANT PACKAGING

The monoimplant is supplied with the micro housing in a sealed envelope that also carries the relevant product information.
The packaging features a double protection to preserve the sterility of the implant subjected to a certified gamma X-ray process.
Part of the label showing the information of the implant is removable for the "Implant Card" or the clinical case sheet of the patient.
A sterility indicator is present on the vial.



TOP LID with safety ring.
An intact top lid guarantees that the product is intact and sterile.

SEALING CAP: ensures airtightness

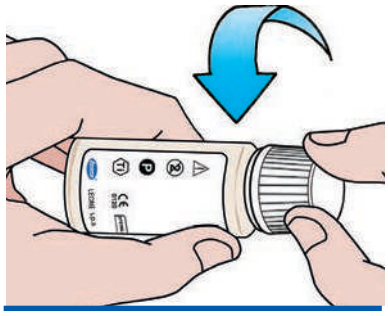
MONOIMPLANT CARRIER: it allows for correct support for the monoimplant and an easy holder for the clinician. It is used to start screwing the monoimplant into the prepared implant site.

MONOIMPLANT

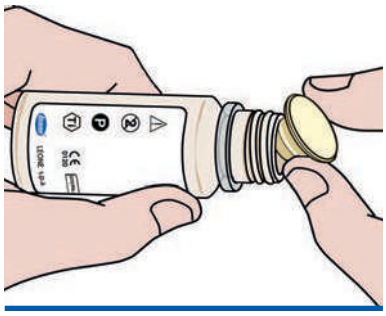
TUBE: contains and protects the monoimplant

VIAL

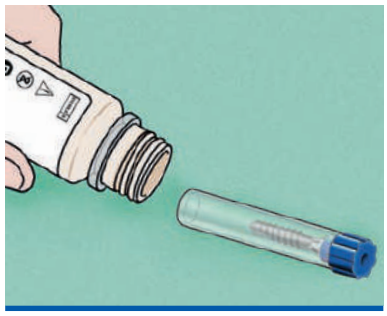
3. INSERTION OF THE MONOIMPLANT



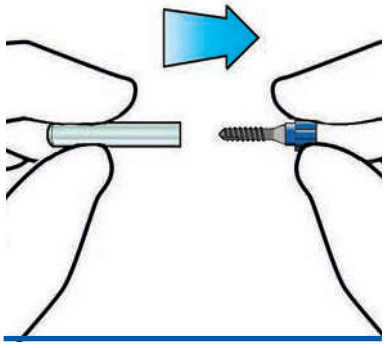
3.1 Unscrew the vial's top lid.



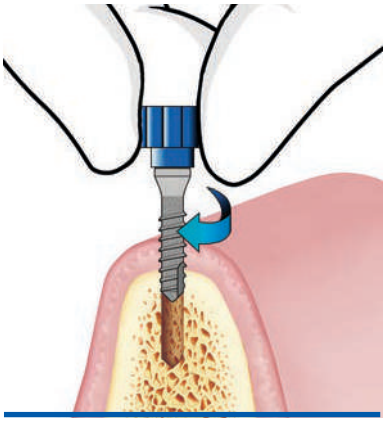
3.2 Remove the sealing cap.



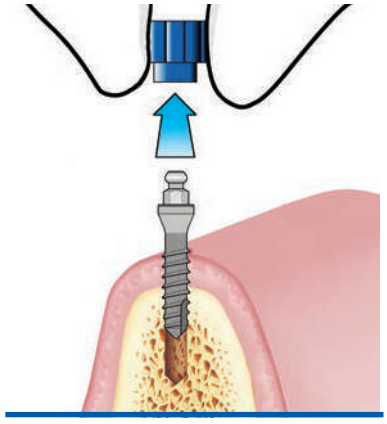
3.3 Extract the tube containing the monoimplant from the vial then lay it gently onto the sterile pad.



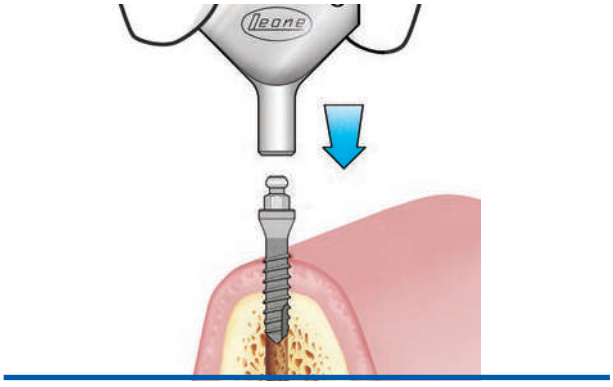
3.4 Hold the tube with one hand while gently pulling out the monoimplant with the other. Hold the monoimplant by the monoimplant carrier.



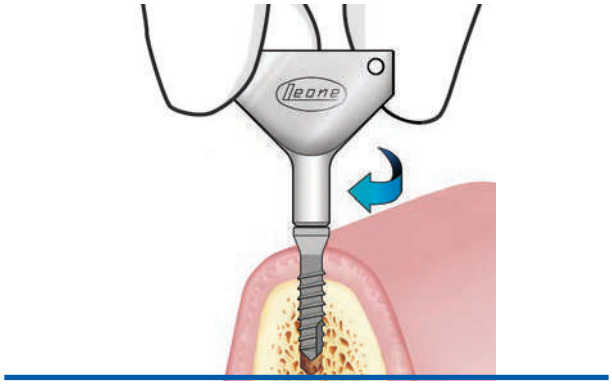
3.5 Still holding the monoimplant by the monoimplant carrier, insert it into the implant site with clockwise movement, while exerting a light downward pressure.
Leone monoimplants are self-tapping.



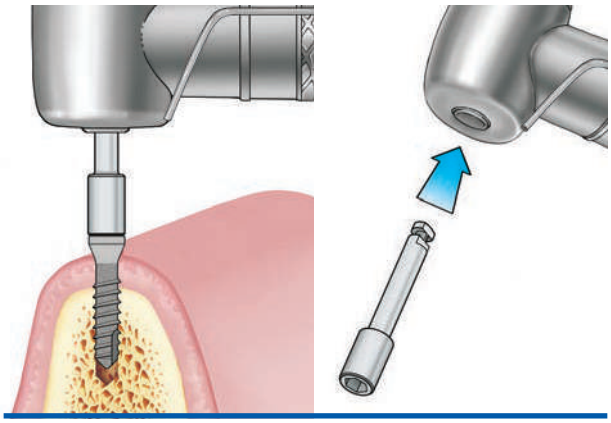
3.6 Remove the monoimplant carrier by pulling up.



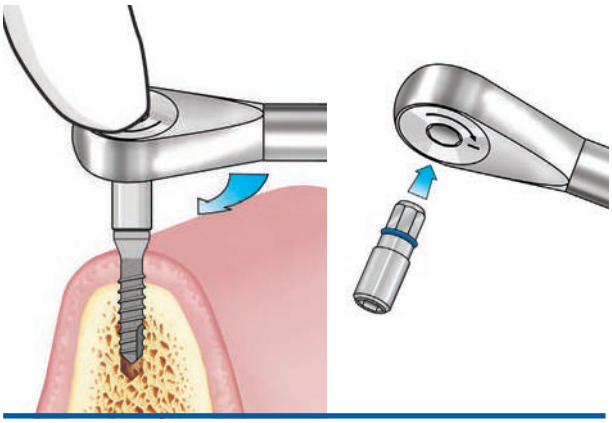
3.7 Position the fan-type wrench onto the head of the monoimplant. The wrench has a hole sidewise for the insertion of a safety leash.



3.8a Screw the monoimplant in with a clockwise motion, until insertion is complete.

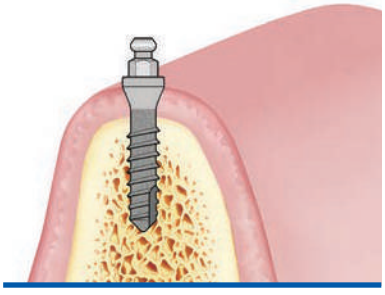


3.8b Alternatively, the monoimplant may be inserted with a contra-angle handpiece, using the contra-angle adapter. Set a micromotor's maximum speed to 20 rpm and a maximum torque value to 50 Ncm.

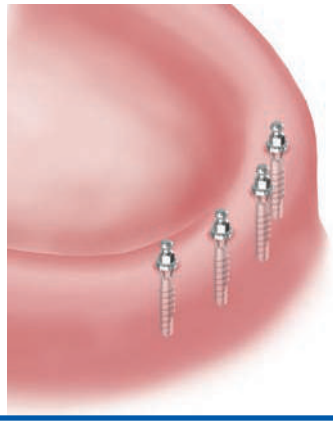


3.9 In case of particularly hard bone, the monoimplant can be inserted with the ratchet, using the specific adapter.

N.B.: Should a ratchet be used to complete the insertion, it is recommended that the clinician should lightly press the head of the instrument with a finger during action, to keep the head perpendicular with the implant.



3.10 Once the monoimplant is in place, the base of the tapered section of the head should sit level with the crestal bone, while the head should stick out of the gum.



3.11 Repeat steps 3.1 – 3.10 for the remaining three monoimplants. Should a flapping technique be used, suture soft tissues around the monoimplants and load implants after healing has taken place. In the meantime relieve the existing prosthesis around the spherical heads of the monoimplants and fill the holes with soft acrylic.

4. PREPARATION OF THE REMOVABLE PROSTHESIS

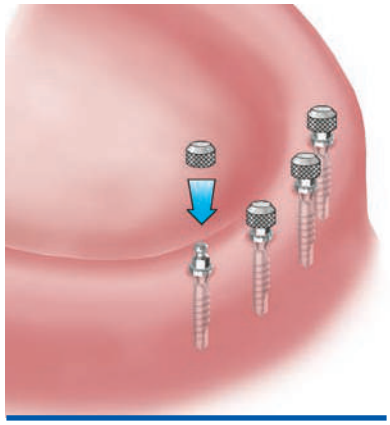
During relining of the pre-existing prosthesis or manufacture of a new one, provide a wide tissue support for the prosthesis. Particular care must be taken to ensure complete tissue support of the prosthesis during the subsequent periodic checks, relining, as needed.

CAUTION: it is recommended to deliver the final prosthesis in the initial phase without housings to allow for adequate tissue adaptation and to correct possible impingements. The clinician will determine the length of the adaptation period.

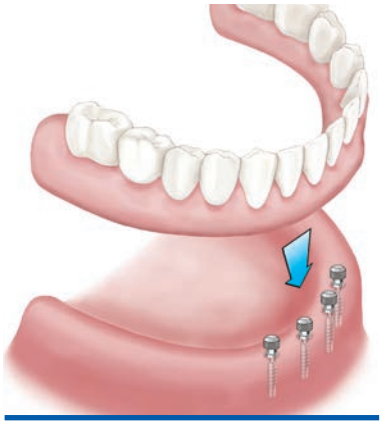
4.1 Once the prosthesis is ready apply some soft wax on the inside surface of the prosthesis or dab the spherical heads of the monoimplants with a marker pen to reveal their location in the prosthesis.

4.2 Using the marks thus obtained in the prosthesis as reference, hollow out the areas needed to adequate diameter to receive the micro housings.

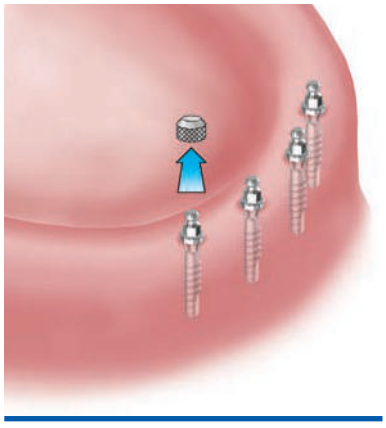
CAUTION: if you are not sure whether the monoimplants have achieved adequate primary stability, we recommend relining the prosthesis with soft acrylic and waiting for a minimum of 3 months for osseointegration before incorporating the housings into the prosthesis.



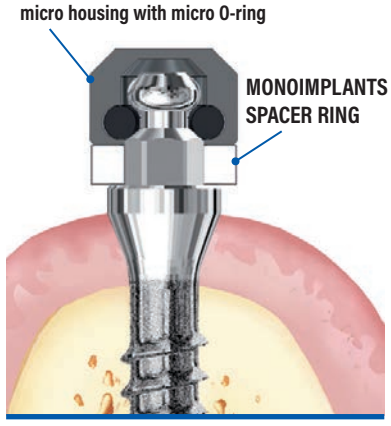
4.3 Place the micro housings on the spherical heads of the implants then press down until seated. Slight lack of parallelism can be overcome by using the housings instead of the micro housings.



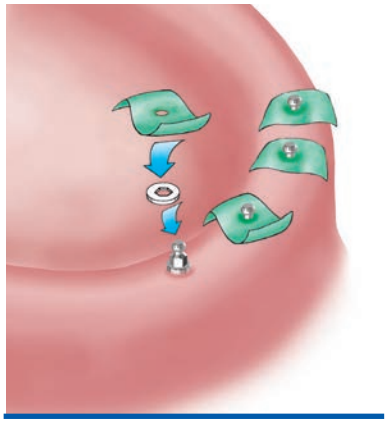
4.4 Insert the prosthesis in the patient's mouth for the final check. It should be free from friction and unwanted contacts. The prosthesis may be relieved corresponding to the micro housings in order to obtain a perfect tissue borne prosthesis without any friction on the housings.



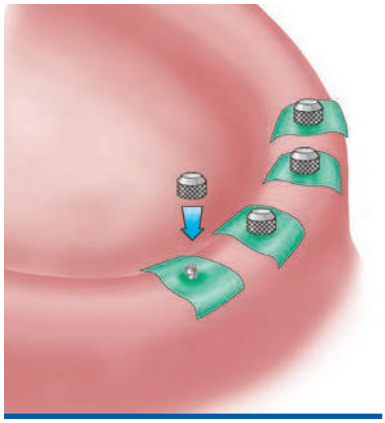
4.5 Remove the prosthesis and micro housings from the implants.



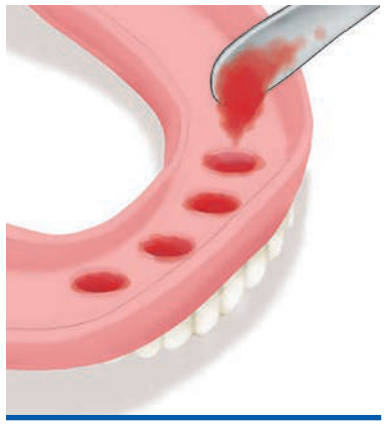
4.6 Place the white spacer ring over the monoimplant. This spacer ring is used to correctly position the micro housing, or the standard housing, into the prosthesis and minimize acrylic seeping into the undercuts of the spherical heads of the monoimplants.



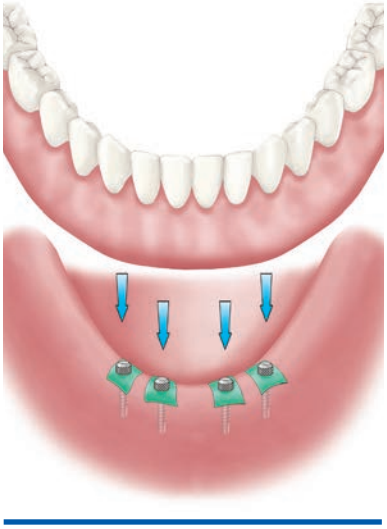
4.7 Place squared pieces of rubber dam over each monoimplant to avoid a direct contact between the soft tissue and the acrylic.



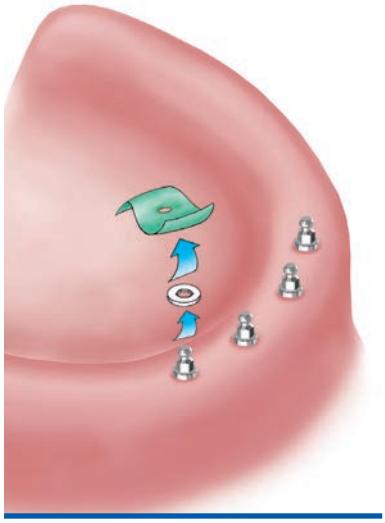
4.8 Place the micro housings onto the monoimplants. Please remember that all housings should be incorporated into the prosthesis at the same time. Do not attempt to place them individually.



4.9 Fill the 4 cavities in the prosthesis with self-curing acrylic and also on the micro housings.



4.10 Fit the prosthesis in the mouth of the patient looking for adequate occlusal contact. The patient should not close the mouth too tightly.



4.11 After the polymerization of the acrylic has been completed, the prosthesis is removed from the patient's mouth. The micro housings, due to their highly retentive surface, are kept in the prosthesis. Remove the rubber dams and the spacer rings from the monoimplants' heads.

4.12 Remove any acrylic excess until the edges of the micro housings are completely exposed. Correct any discrepancies that may interfere with proper seating of the appliance. Finish and polish the prosthesis.

Prosthesis maintenance

Patients should be seen at least once every six months. Review should include assessment of prosthesis retention and replacement of damaged O-rings. In case of prosthesis relining, at the end of the procedure always replace the O-rings. If a simple prosthesis relining procedure is insufficient and it is necessary to reincorporate the metal housings into the prosthesis, remove the housings with a small bur and replace them with new housings following the above-mentioned procedure (points 4.6 – 4.12). Please remember that all the housings within the prosthesis should always be reincorporated together into the prosthesis and not only one or part of them.

Replacing an O-ring

When replacing an O-ring, remove the old O-ring from the metal housing and lubricate the new O-ring with silicone spray or Vaseline to facilitate placement within the metal housing. Insert the new O-ring into the housing by using plastic forceps. Use a round-shaped instrument which can enter into the hole of the O-ring to push it into its seat with small circular movements. To improve visibility we recommend to work using a magnifier with a magnification of at least 4x.