surgical and PROSTHETIC procedure

for



monoimplants for overdenture O-ring





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.

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 necessary.

Objective exam

It consists of:

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

Radiographic exams

PANORAMIC RADIOGRAPH: frequently, this radiograph enables to appraise 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 Cat. 156-2003-01 (page 50) 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 instrument for radiographic examinations (CT and panoramic radiograph). Superimpose the template to the radiograph in order to select the monoimplant in relation to the quantity of bone available.



To simplify the surgical operation, an instrument organizer Cat. 156-0017-00 (page 49) was conceived by LEONE to sterilize and hold the necessary instruments on the operating table. The organizer must be sterilized before use.

The sterilization must be performed as follows:

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







1) 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.



1.1 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 eventual inclination of every single implant shall not have to overcome 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 have to act exclusively as a retentive element.



1.2a Flapless procedure

Punch the mucosa with the use of the special mucosa punch for handpiece (Cat. 151-2215-20) included in the organizer. Use the mucosa punch with the handpiece set to low speed (approx. 40 rpm). Use 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. Remove the mucosa punch and remove 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 the flapping 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 obtained, use the round bur Cat. 151-1934-01 included in the organizer, to mark the cortical bone for the subsequent pilot drill. Alternatively, it is possible to use the lance drill Cat. 151-1930-02, which is particularly suitable in case of narrow knife-edged ridges.



1.4 Place the Ø 2.2 mm pilot drill Cat. 151-2241-12, included in the organizer, in the track made by the round bur and drill the bone until the length of the desired monoimplant has been reached. The handpiece must be set to a limited speed of 800 rpm. Irrigate abundantly while using the pilot drill. Pay attention to the length of the monoimplant, to which the height of the soft tissues has to be added. The drilling depth can be checked on the depth marks on the drill:

- drills with 4 marks: 8-10-12-14 mm

- drills with 5 marks: 6.5-8-10-12-14 mm

Care must be taken to the length of the monoimplant to which the height of the soft tissues shall be added.



1.5 Insert the depth gauge Cat. 156-2002-00, included in the organizer, into the newly created implant site to check its depth, considering also the height of the soft tissues.



1.6 Repeat points 1.2 - 1.5 for the remaining 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 Cat. 156-2004-00 and the depth gauge both included in the organizer; these may be inserted in the implant sites just drilled. The measuring pins may also be used at any other time to check soft tissue thickness.



1.7 It is now time to 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.





The monoimplant is supplied with the micro housing in a sealed envelope that also carries the relevant product information.

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 125) is to be applied on the "Identity card" of the implant or on the clinical case sheet of the patient. A sterility indicator is present on the glass vial.

THE GLASS VIAL



2) LEONE MONOIMPLANT PACKAGING





3) INSERTION OF THE MONOIMPLANT





3.1 Unscrew the glass vial's top lid.



3.2 Remove the sealing cap.



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



3.4 Hold the vial 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 (Cat. 156-1015-00), included in the organizer. Its opening is engineered to fit the hexagonal head of the monoimplant with precision. This wrench presents a hole sidewise for the insertion of a safety leash.



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





3.8b Alternatively, the monoimplant may be inserted with a contra-angle, using the special adapter (Cat. 156-1017-00) included in the organizer as well. 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 Cat. 156-1014-00, using the appropriate adapter Cat. 156-1016-00.

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 in correspondence of 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 has to be paid also to the correct tissue support of the prosthesis during the subsequent periodical checks, carrying out prosthesis relining, if necessary.



CAUTION: *it is recommended to deliver the final prosthesis in the initial phase without housings to the patient 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 Use the marks thus obtained in the prosthesis as reference; create the cavities with 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 home. Slight lack of parallelism can be overcome by using the housings Cat. 123-0002-00.



4.4 Insert the prosthesis in the patient's mouth for the final check. Occlusion should at this point be free from friction and unwanted contacts. The prosthesis may be relieved in correspondence of the micro housings' cavities 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 over each monoimplant the specific white spacer ring. Please remember that this white spacer ring is used to incorporate the micro housing with 0-ring Cat. 123-0003-00 or the housing with 0-ring Cat. 123-0002-00 into the prosthesis. The spacer rings allow a precise incorporation of the housings into the prosthesis without displacements, promote a correct resilient retention of the prosthesis and protect the undercuts of the spherical heads from acrylic.







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 at the same time into the prosthesis and not at different moments.



4.9 Fill the 4 cavities in the prosthesis with self-curing acrylic and as may be the case put the acrylic also on the micro housings.



4.10 Fit the prosthesis in the mouth of the patient looking for adequate occlusal contact. The patient at this stage should not try to close his/her 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 cause impingement problems. Finish and polish the prosthesis.

For replacing an O-ring and prosthesis maintenance, please refer to the indications on page 97.