



LEONE MONOIMPLANTS FOR O-RING OVERDENTURE

Surgical and Prosthetic procedures

Acknowledgement

LEONE SpA. would like to acknowledge the invaluable contribution of Dr. Leonardo Targetti, whom we thank sincerely, towards the completion of this manual.

Disclaimer

The surgical procedures described hereafter for the placement of the Leone Mono Implant system are for the exclusive use of qualified Dental Surgeons, Oral Surgeons, Prosthodontists, Periodontists and Maxillofacial Surgeons. The following instructions are not meant to replace the knowledge and expertise of legally qualified professionals, but are to be taken by the Dental Surgeon exclusively as generic information; He/She (The Dentist) will remain entirely responsible for the outcome of his therapeutic procedures. Initial patient Anamnesis, Diagnosis and all the laboratory tests necessary towards the outlining of a treatment plan, must be determined solely by the Surgeon who will perform surgery on the patient.

Patient evaluation and diagnosis:

Before performing a surgical implant intervention, it is essential to assess the general health state of the patient. A careful Patient Anamnesis is therefore always recommended prior to treatment planning involving Monoimplants.

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MONOIMPLANT SELECTION

Our choice of the appropriate Monoimplant size (implant length and transmucosal neck length) is 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

A **template** (cat. 156-2003-01) is available that shows all Leone Monoimplants 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). By simply superimposing the Template to the radiograph and depending on the quantity of bone available the Clinician can choose the right Implant size for each Patient.

Leone Monoimplants are made of grade 5 Titanium for surgical use, with an outer diameter (**D**) of 2, 7 mm. Four lengths (**L**) of the endosseous part are available: 10-12-14-16 mm. Additionally, two gingival heights (**GH**) (3.0 mm and 5.0 mm) are available.

The Monoimplant body is finished with a special sandblasting process, ensuring an optimal surface roughness ($Ra = 1 \mu m$). The Micro Socket is made of grade 5 Titanium for surgical use, with an outer diameter of 4, 2 mm (**d**) and height of 2, 8 mm (**h**).

SURGICAL PROCEDURE

The ORGANIZER KIT

The ORGANIZER (156-0017-00) KIT seen in the photo allows the Clinician to easily manage and sterilize the instruments necessary for the planned intervention.

These are the instruments in the Organizer, from left to right in the photo:

1. 1 Round Bur
2. 1 Mucotome for contra-angle
3. 1 Pilot Drill
4. 1 Depth Gauge
5. 2 Measuring Pins for gingival thickness
6. 1 Handpiece Adapter
7. 1 Fan-type (or 'Butterfly') Wrench

The fan-type wrench, the depth gauge and the measuring pins for gingival height are equipped with a safety hole should accidental swallowing of any of the pins occur.



Sterilization must be performed as follows:

1. Wrap the Organizer into a sterilization bag as requested by the manufacturer of the sterilizing machine
2. Autoclave at 121 °C (249 °F) for 20 minutes
3. Remove the Organizer from the machine and leave it to cool inside the bag
4. Keep the organizer inside the bag to preserve sterility

1 – PREPARATION OF THE IMPLANT SITE

1.1 - After adequate treatment planning, clearly mark the locations where the monoimplants must be inserted with a marker pen or a surgical template.

Leone Monoimplants must only be inserted in the Mandible, at the level of the Mandibular Symphysis, located in the area between the (foramen) two **halves**.

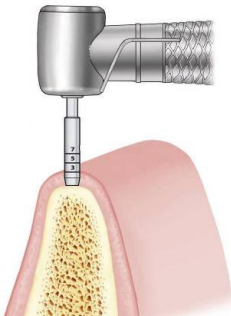
The number of Monoimplants required to adequately support a removable prosthesis is 4. The minimum required space between each implant and the next is 6mm. This will also allow the correct positioning of the Socket housings.



- Place the 4 Monoimplants at 6.00mm minimum from each other

1.2a – Flapless procedure

Punch the mucosa with the use of the special Mucotome for Handpiece (cat.151-2215-20) Use the Mucotome with the Handpiece set to low speed (approx. 40 rpm). Drill down until bony tissue is met.



- Using the Mucosa Punch for the 'Flapless' Technique

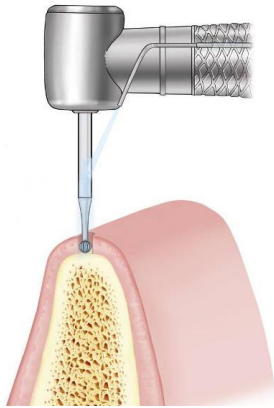
For visual reference, as well as to determine the gingival thickness around the implant area, you can use the three black lines clearly visible around the Mucotome, at the heights of 3-5-7 mm starting from the crest bone.

****The pictures and information illustrated in this page are for informative purposes only and they are not intended to constitute therapeutic advice for the Dental Surgeon, the Specialist Dentist or the Patient. Leone SpA. does not assume any responsibility regarding the accuracy on the information described in this issue.**

1.2b – 'Flap' procedure

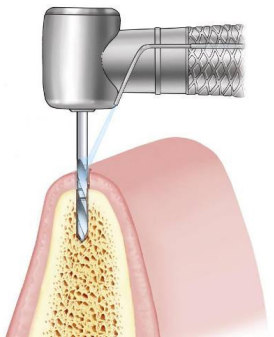
In case there are uncertainties on the crestal bone's condition or on the quantity of bone available, the use of a procedure with 'Flap' is advisable. Start with a scalpel incision of the soft tissues, then open the gingival flap for a clearer vision of the crestal bone: the osteotomy can now be performed.

1.3 – Once the gingival tunnel has been obtained, use the Round Bur (cat. 151-1934-01) to create a track for the pilot drill on the cortical surface of the bone.



- Round Bur with Spherical Head

1.4 - Place the Pilot Drill (cat. 151-2241-12, Ø 2, 2 mm) 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 maximum speed of 800 rpm. Pay attention to the length of the monoimplant, to which the height of the soft tissues has to be added. You can check your depth by looking at the notches on the drill shaft. Flush abundantly with water while using the pilot drill.

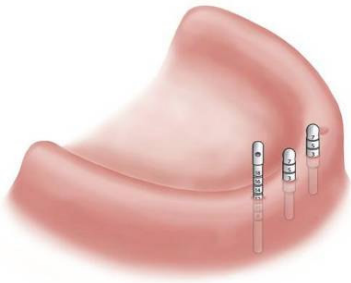


- Pilot Drill

1.5 – Insert the Depth Gauge (cat. 156-2002-00) in the newly created implant site to check its depth. If you are performing a 'Flap' technique, consider your gummy tissue thickness before you move on to the following step in the procedure.

1.6 – Repeat points 1.2 thru 1.5 for the remaining three monoimplants, ensuring the maximum degree of parallelism among the surgical alveoli.

Check the parallelism of the Monoimplants using the Measuring Pins for gingival height (cat. 156-2004-00) and the Depth Gauge; these may be inserted in the implant sites you just drilled. The Measuring Pins may also be used at any other time to check gum tissue thickness.



- Using the Measuring Pins to check parallelism and depth.

1.7 - It is now time to choose the appropriate Transmucosal Neck height of your Monoimplant.

IMPORTANT: The head of the monoimplant must protrude from the gingiva by at least 1.00mm to avoid a possible impingement of the micro Socket on the Patient's soft tissues.

2 – LEONE MONOIMPLANT PACKAGING

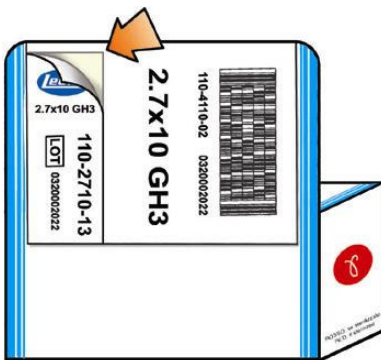
The Monoimplant with its 'companion' Micro Socket is supplied pre-sterilized in a sealed envelope that also carries the relevant product information.

2.1 – The Box

The label on the Box shows the Monoimplant dimensions: diameter, length and Transmucosal Neck Height. A red dot indicating that the product is supplied pre-sterilized is also visible.

2.2 – The Label

The label on the package shows the product code, all the symbols required by the current Health regulations and the batch number. Part of the label is removable, allowing the physician to include it in the patient's case file.



- Leone Monoimplant. The arrow shows the removable label on the Box.

2.3 – Plastic Jar



intact and safe to use.

-The top lid is equipped with a safety ring. An unbroken safety ring is your guarantee that the product is



Sealing Cap. →

This ensures the product is stored airtight.

Implant Carrier: this innovative solution allows the Clinician to remove the Implant from the Glass Phial and to start screwing it into the prepared implant site with one, flowing motion.

Glass Phial (below). This contains the Monoimplant, protecting it from any contact with the outside.



-Each Leone Monoimplant is supplied sterile in a Glass Phial. Use the blue Carrier to remove it from the Phial and to start screwing it in.

3 – INSERTION OF THE MONOIMPLANT

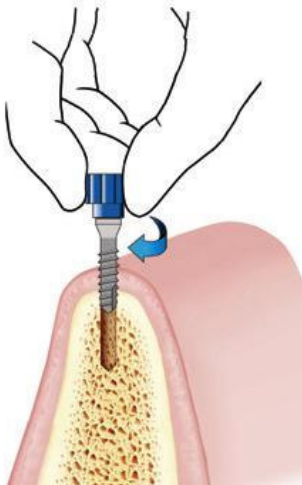
3.1 – Unscrew the bottle's cover cap.

3.2 – Remove the Sealing Cap.

3.3 - Extract the Glass Phial containing the Monoimplant from the bottle, then lay it gently onto the sterile pad.

3.4 – Hold the Glass Phial with one hand while gently pulling out the Monoimplant with the other. Hold the Monoimplant by the blue Implant Carrier.

3.5 – Still holding the Monoimplant by the blue Carrier, insert it in the implant site with clockwise movement, while exerting a light downward pressure. Leone Monoimplants are self-threading.



3.6 – Remove the implant Carrier Cap simply by pulling upwards.

3.7 – Position the 'Butterfly' Wrench (cat. 156-1015-00) - its opening is engineered to fit the hexagonal head of the Implant with precision.

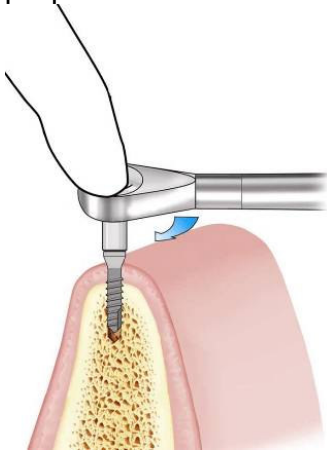


3.8 – Screw the Monoimplant home with clockwise action, until insertion is complete.

Alternatively, the Monoimplant may be inserted with a contra-angle, using the special adapter 156-1017-00.

3.9 - In case of particularly hard bone, the Monoimplant can be inserted with the Titanium Ratchet (cat. 156-1014-00), using the appropriate adapter (cat. 156-1016-00).

Note: 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 instrument perpendicular with the implant.



- using the 156-1014-00 Titanium Ratchet to screw the Monoimplant in

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 passages 3.1 thru to 3.10 for the remaining three monoimplants. Should a ‘flap’ technique be used, the soft tissues must be sutured around the monoimplant. A minimum of 15 days should be allowed towards healing of the soft tissues before an O-Ring Overdenture can be loaded on. In the meantime the prosthesis can be trimmed in correspondence of the spherical heads of the Monoimplants, and the holes can be filled with soft acrylic.

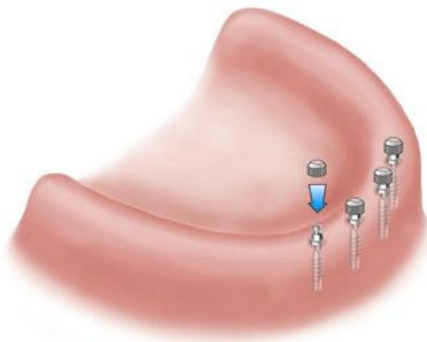
PROSTHETIC PROCEDURE

1 – Apply some soft wax on the inside surface of the prosthesis or dab the spherical heads of the mono implants with a marker pen to reveal their location in the prosthesis.

2. Use the marks thus obtained in the prosthesis as reference; create the housings that will eventually accommodate the Micro-Sockets. Bear in mind the measurements for the Micro-Sockets are 4.2mm width x 2.8mm height.



3 – Place the Micro Sockets on the spherical heads of the implants then press down until home. Slight lack of parallelism can be overcome by using the 123-0002-00 Micro Sockets.



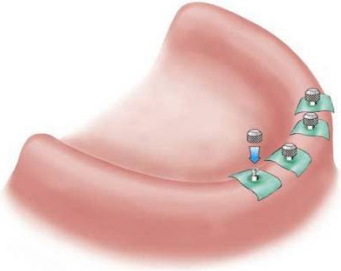
4 - Insert the prosthesis in the patient's mouth for the final check. Occlusion should at this point be free from friction and unwanted contacts. The prosthesis may be trimmed in correspondence of the Micro Sockets' locations for maximum support.



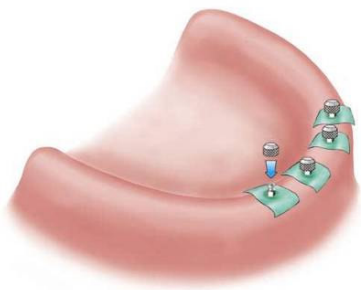
- Final 'Comfort Check'.

5 – Remove the prosthesis and Micro Sockets from the implants.

6. Place a small square of dental dam around every implant, at the level of the hexagon, to avoid the soft tissues coming in contact with the acrylic.



7 – Place the Micro Sockets back on the 4 Implants again.

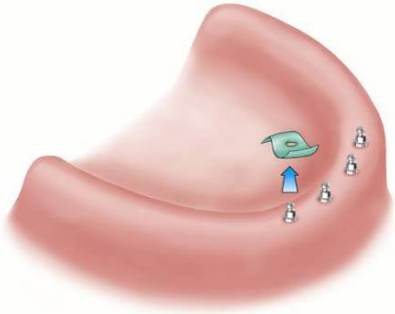


8 – Fill the 4 housings in the prosthesis with self-curing acrylic.



9 - 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 hard.

10 - At the end of the acrylic's curing process, remove the prosthesis from the mouth of the patient. The Micro Sockets, thanks to their extremely retentive surface, will be captured by the prosthesis. Remove the dams from the heads of the Monoimplants.



11 - Remove any acrylic excess until the edges of the Micro Sockets are completely exposed. Correct any discrepancies that may cause impingement problems. Finish and polish the prosthesis.

LEONE Monoimplants for O-Ring Overdenture

Packaging and replacement parts

Each Box contains: 1 Monoimplant and 1 Micro Socket with O-ring for Overdenture.

REPLACEMENT PARTS FOR MONOIMPLANTS


Part Code	Description	
123-0003-00	MICRO SOCKET WITH O-RING Pack of 1	
123-0001-01	O-RING FOR MICRO SOCKET	Pack of 2
156-0017-00	ORGANIZER KIT FOR MONOIMPLANTS Composition: 1 Round Bur 1 Mucotome for Contra-Angle 1 Pilot Drill (long) Ø 2, 2 mm 1 Depth Gauge Ø 2, 2 mm 2 Measuring Pins for gingival thickness 1 Adapter for Handpiece 1 'Butterfly' Wrench for Monoimplants	
151-2215-20	MUCOTOME For Contra-Angle	
156-2004-00	MEASURING PIN FOR GINGIVAL HEIGHT Diameter 2, 2 mm	
156-2002-00	DEPTH GAUGE □ Diameter 2, 2 mm	
156-1015-00	'BUTTERFLY' SCREWDRIVER	
156-1017-00	ADAPTER For Headpiece	
156-2003-01	TEMPLATE	
156-1016-00	ADAPTER For Ratchets	

TABLE 1 Leone Monoimplants with 3.00mm Transmucosal Neck









				
altezza tratto transmucoso	3 mm	3 mm	3 mm	3 mm
\emptyset	2,7 mm	2,7 mm	2,7 mm	2,7 mm
lunghezza	10 mm	12 mm	14 mm	16 mm

TABLE 2 Leone Monoimplants with 5.00mm Transmucosal Neck

				
altezza tratto transmucoso	5 mm	5 mm	5 mm	5 mm
\emptyset	2,7 mm	2,7 mm	2,7 mm	2,7 mm
lunghezza	10 mm	12 mm	14 mm	16 mm