ML®
IMPLANT SYSTEM

www.mlimplantsystem.com.ar

IMPLANT SYSTEMS **SHe**, **SHi**, **SRi** y **SHi Cortical**

1-DESCRIPTION

The ML IMPLANT SYSTEM® dental implants are manufactured in Titanium grade 4 CP (norm EN ISO 5832/2) and present a rough surface in their contact area, which has been obtained by chemical and mechanic treatment. The ML IMPLANT SYSTEM® dental implants have been designed and manufactured under strict national and international standards.
Interface connection:
SHE System: External hexagon connection of 2,7 mm (platform model Ø4 and Ø5) and 2, 5 mm (platform model 3, 45).
SHI and SHI Cortical System: Internal hexagon connection of 2, 4 mm.
SRI System: Tri-channel internal connection.

2-INTENDED USE

The ML IMPLANT SYSTEM® dental implant is a titanium device, surgically placed in the upper or lower jaw bone, which behaves analogous to a root of a natural tooth, creating a stable and resistant support for the prosthetic components.

3-PRESENTATION

The dental implant comes in two versions, pre-mounted (implant, closing cap, and fixture-mount) and unmounted (implant and closing cap).
Both versions are protected by a thermo-shrinkable package, to prevent any opening by accident, together with three labels bearing the product description so as to keep its traceability.
The primary container is air tight so as to prevent any contamination after gamma radiation sterilization.

Precaution: The sterility of the dental implant is ensured until the opening of the secondary container opening, thus, it needs to be immediately opened before its placing, in a completely aseptic environment (according to current regulations and standards)

Warning: The product must not be used after its expiration date (printed on the label) or if the container happens to be damaged.

Warning: The dental implant must be used only once, thus, it must not be re-used or re-sterilized. The product reuse can bring about possible deterioration of its features, risk of tissue infection and/or deterioration in the patient's health.

Note: If you wish to obtain further information, consult the ML IMPLANT SYSTEM® catalogue (www.mlimplantsystem.com.ar).

4-INSTRUCTIONS FOR USE

Warning: The dental implants must be placed by professional dentists counting with adequate training.

Precaution: Before any surgical procedure, a comprehensive evaluation of the patient must be carried out, together with a pre-surgical diagnosis, a determination of the surgical site for the implant placement, through the adequate radiological techniques and appropriate treatment planning.

Precaution: Failure in planning can lead to failure in treatment. Each professional must assess if the treatment is the appropriate one, basing themselves on their training and personal experience.

Precaution: The model, diameter, size, position and implant quantity must be chosen for each clinical case, bearing in mind the anatomy and available space. Also, the bone quantity and quality must be taken into account.

a-Dental milling
Select the drill sequence and depth according to the planned implant. The dental milling must be carried out at high speed (between 800 and 1200 RPM) with abundant and constant irrigation of sterile saline solution at room temperature.
Precaution: The drills must be in good condition, clean and sterile. The depth of the milling must be controlled during all the sequence.

IMPLANT MODEL	SUGGESTED DRILLING SECUENCE										
	Lanza	Ø2.0	Piloto	Ø3.0	Ø3.15	Ø3.3	Ø3.5	Ø3.8	Ø4.2	Ø4.3	Ø4.5
SHE	->	->	->	Ø3.45	->	Ø3.75	Ø4.0	->	->	Ø5.0	->
SHI	->	->	->	->	Ø3.3	Ø3.75	->	Ø4.2	->	->	Ø5.0
SHI Cortical	->	->	->	->	Ø3.75	->	->	Ø4.2	->	->	->
SRI	->	->	->	Ø3.5	->	->	->	Ø4.3	->	->	Ø5.0

Note: the pilot drill could be replaced, adding to the sequence of the drills of Ø2.5 and Ø2.8. For further information, consult the ML IMPLANT SYSTEM® catalogue (www.mlimplantsystem.com.ar).

b-Container opening and implant placement
Remove the container form the cardboard packaging. Break the thermo- shrinkable sealing and tip over the primary container over the sterile work area.
Unmounted Implant: Remove the silicone plug, and by means of the fixture mount driver for contra angle or the ratchet wrench, take out the implant from the container. Place it on the surgical site, ideally at low speed (25 rpm at most) or by means of a torque wrench.

Pre- mounted Implant: Remove the silicone plug. Tilt the primary container so as to overturn the implant over your hand. Place the implant on the surgical site by carrying out the first turnings manually. Remove the blue knob and finish the placement by means of a torque. Rome the third mounting by means of a hexagon screw 0,050".
The maximum insertion torque of the dental implant is 45 N.Cm. If the implant gets stuck during its placing or if it reaches an insertion torque of 45 N.Cm before it is fully settled, turn the implant anti-clockwise and remove the implant from the surgical site and place it on the container. Go over the surgical site with a bigger drill, a counter sink or a handed clean out tap tool, depending on the implant model or each individual case.
Once the implant has been placed, according to the chosen surgical protocol, place the closing cap or abutment and stitch up.

Precaution: Once the implant has been removed from its hermetic container, it needs to be immediately taken to the mouth cavity. .

Warning: An excessive implant torque can lead to its damage, or, fracture or necrosis in the surgical site.

NOTE: If you wish to obtain further information about the usage indications , consult the ML IMPLANT SYSTEM® catalogue (www.mlimplantsystem.com.ar).
To ensure the long-term result of the treatment, it is recommended to provide a complete and regular follow-up of the patient after the treatment with implants and inform about the appropriate oral hygiene. These orientations are under the responsibility of each professional.

5-PRECAUTIONS

The success of the implant cannot be guaranteed to 100%. Failures could occur, especially, whether the work procedure or the indicated usage limitations are not respected.
The bone must hold enough dimensions (in width and height) so as to obtain a good primary stability.
As a general rule, the implant of greatest diameter must be used, if possible.
Selection criteria: Not only the local and systematic contraindications must be analyzed, but also the "normal" healing capacity, the efficient oral hygiene, the present healthy teeth, the growth of the jaw and jawbone, once already concluded, the general health condition of the patient and the presence of enough healthy maxillary bone.
Special care must be taken when spotting: blood vessels, maxillary sinuses, nerves and their endings, nasal cavities, soft tissue spaces, as extremes to be taken into account for the surgery planning.
Special care must be taken to patients with: bone metabolism disorders, non- cooperative or demotivated patients (alcoholism or drug addictions, psychosis, psychiatric disorders which interfere with understanding or the fulfilment of the correct procedures),a previously irradiated bone, diabetes, bruxism, parafunctional habits , smoking, chronic kidney disease, some chronic heart or vascular disease, chemotherapy treatments, insufficient oral hygiene, local radicular remains , local oral diseases, xerostomia, use of steroid / anticoagulant/ immunosuppressant / bisphosphonates medication, connective tissue disease, or periodontitis. The treatment in this kind of patients is under the responsibility of each professional.
The inadequate surgical and/or prosthetic planning can compromise the performance of the implant systems, resulting in failures such as loss or fracture of the implant, loosening or screw breakage of the prosthetic component.
Neither the altering nor the modification of the implant must be tried.
Due to the small size of the components and instruments, special care must be taken so the patient does neither swallow or aspirates them by accident.
Make use of original prosthetic components and instruments in good conditions from the implant system of ML IMPLANT SYSTEM®.
Neither the safety nor the compatibility of the ML IMPLANT SYSTEM® dental implants have been evaluated within the environment of magnetic resonance. Not any heating test, displacement test or test of image artifacts have been carried out within the environment of magnetic resonance. The scanning of this product could bring about damage to the patient.

6-CONTRAINDICATIONS

The placing of the dental implants of ML IMPLANT SYSTEM® are contraindicated for the following patients:
Those who do not gather the necessary medical conditions for a surgical dental procedure.
Those cases where the number, appropriate size or desired position of the dental implants for a safe support of the functional or parafunctional loads cannot be reached. Those who are allergic to titanium or bear incomprensible hyper-sensitivity, those with an unfavorable bone anatomy, or with not enough available bone (less than 2mm around the implant), or with an inadequate bone quality, pregnancy and breastfeeding.

7-SIDE EFFECTS

Failure in the implantation sequence can result in the following complications: infection, bone loss, dissatisfaction on behalf of the patient, implant movement, local soft tissue degeneration and location or unfavorable implant alignment. The treatment for these reactions must follow the procedures indicated for natural dentition.
After the period immediately subsequent to implant insertion, any activity involving high physical effort must be avoided.
Some consequences of the surgery can occur such as swelling, pain, edemas, bruising, etc., but they are expected to happen during a short period. However, implant movement, bone loss or chronic infection can indicate failure in the implantation and must be treated as soon as possible. If implant removal happens to be needed, all the soft tissues in the placing of the implant must be removed and the same procedure as a traumatic dental extraction must be carried out.
In some cases, the unfavorable location or alignment can be corrected by means of angulated connectors or be tailor-made. If not, the implant may be replaced or relocated.

8-CLEANING AND STERILIZATION

The ML IMPLANT SYSTEM® dental implants are supplied sterilized together with their closing cap and mount.

The instruments are supplied without being sterilized and must be cleaned and sterilized before being used.
It is recommended to sterilize in an autoclave following the guidelines established under the ISO 17665 standard, with the following parameters: 121º C during 15 min.

Warning: The ML IMPLANT SYSTEM® instruments must be withdrawn from the original container and be placed in envelopes, bags or in coils indicated for the sterilization processes by autoclave.
The sterilization must be carried out either on the eve or on the day of intervention.

NOTE: For the complete set of recommended parameters, consult the parameters de ML IMPLANT SYSTEM® catalogue (www.mlimplantsystem.com.ar)

9-STORAGE CONDITIONS

The product must be stored in its original container, in a dry and clean place, at room temperature (15°C - 25ºC) and protected from sunlight and any heat source.

10-FINAL DISPOSAL

All the consumable products and materials used during the surgery for the placing of the dental implant could jeopardize the health of those who handle them, after being used. Before disposing them in the environment, it is recommended to consult and comply with the current legislation.

11-USED SYMBOLS

LOT	Lot number		Manufacturer information		Consult instructions for use		Single user
EC REP	authorized representative Data		Date of manufactured		Keep dry		Do not Resterilize
STERILE R	Sterilized by gamma irradiation		Use before		Keep away from sunlight		Do not use if package is damaged
				15° 25°	Temperature limit		

12-MANUFACTURED BY

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