ML®
IMPLANT SYSTEM

www.mlimplantsystem.com.ar

IMPLANT SYSTEM ABUTMENTS
SHe, **SHi**, **SRi** y **SHi Cortical**

1-DESCRIPTION

The ML IMPLANT SYSTEM® prosthetic pieces and accessories have been designed and manufactured under strict national and international standards to be used together with dental implants.
The prosthetic pieces are devices manufactured in Titanium grade 4 CP (norm EN ISO 5832/2) that, through their interface connection, are connected directly to the dental implant as support to the prosthetic rehabilitation.
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 prosthetic component is part of the implant system which supports and/or retains the prosthesis or a superstructure.
Healing abutment and closing screw: They are temporarily used, during the scarring process of soft tissues.
Cemented prosthesis: The support or base for the anchoring of crowns or cemented superstructures.
Screwed Prosthesis: It is the support or base for the anchoring of crowns or screwed superstructures.
Removable Prosthesis: It is the support or base for the anchoring of crowns or removable superstructures.
Accessories: They are the necessary components and accessories to take the analogue or digital dental impression.

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

3-PRESENTATION

The ML IMPLANT SYSTEM® prostheses and accessories are presented in pouch with regulatory label, by unit, non- sterile

4- INSTRUCTIONS FOR USE

Warning: ML IMPLANT SYSTEM® products must be placed professional dentists counting with adequate training.

Warning: The prosthetic components must be sterilized before their use (See point 9).

Warning: The product must not be either 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.

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.

a.Choose the adequate prosthesis and check the free occlusal clearance.

b.Connect the implant and adjust by means of the corresponding screw.
Precaution: Never exceed the recommended torques (See point 5). An excess in torque can lead to the device breakage.

c.Check the correct seating of the prosthesis with the dental implant.

Precaution: Neither any free space nor any gap must be left between both pieces.
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.

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

5-RECOMMENDED TORQUES

TORQUES	DEVICES
MANUAL	HEALING ABUTMENT, CLOSING SCREW, IMPRESSION COPPING
12 N.cm	SCREWS FOR COFIAS
20 N.cm	O'RING ABUTMENT, EQUATOR ABUTMENT, LOCKING SCREW
32 N.cm	OTHER ABUTMENTS AND SCREWS

6-PRECAUTIONS

Make use of original components and instruments in good conditions from the implant system of ML IMPLANT SYSTEM®.
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.
Neither the safety nor the compatibility of the ML IMPLANT SYSTEM® prosthetic components 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.

7-CONTRAINDICATIONS

The prosthetic components that are used for the rehabilitation of the ML IMPLANT SYSTEM® dental implants are contraindicated to 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 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 or breastfeeding.

8-SIDE EFFECTS

Failure during planning or selection or during the sequence of the placing of the prosthesis can result in: breakage of some of the components, screw loosening or dissatisfaction of the patient.

9-CLEANING AND STERILIZATION

It is recommended to sterilize in an autoclave following the guidelines established under the ISO 17665 standard, with the following parameters: 121° C during 15 min.

Warning: The ML IMPLANT SYSTEM® prostheses and accessories 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)

10-STORAGE CONDITIONS

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

11-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.

12- USED SYMBOLS

LOT	lot number		Manufacturer info		Read Instructions for use	2	Do not reuse
EC REP	Authorized representative info		Manufacturing date		Keep Dry	15 25	Temperature limit
NON STERILE	NON STERILE product		Due date		Keep away from sunlight and other heat sources		Do not use if packaging is damaged

13-MANUFACTURED BY

STEELDEC S.A.
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Technical Director: Pharmacist: Claudio Cocozza MN: 15385 / MP: 18716

CE 2460

Medic product´s registry number: PM-1953-1

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