ORTHODONTIC
MINI IMPLANTS
and
INTRA-EXTRAORAL







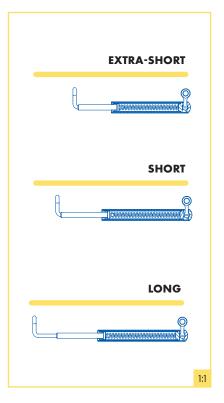




CLASS II CORRECTOR (patented)

The non-compliance device for Class II correction.

The small sizes of the device allow for optimum patient comfort while the constant and light force delivered by the spring **MEMORIA**° 200 g, located inside the plunger, stimulates the mandibular advancement. In this new version, the fluidity of movement and the strength of the telescopic mechanism are improved. The packages include all the needful parts for the application of a bilateral correction device.



Available in **3 lengths** with both mesial and distal fitting to upper molar tube, for a total of 6 possible positions in the mouth. When used in the mesial position, it can be placed on a single direct-bonding tube without the need of band or round tube.

mesial support

to vestibular tube

distal anchorage

to vestibular tube





To avoid breakage, the device should not be mounted at full compression: once in the mouth in habitual occlusion, a portion of the plunger coming out of the tube for at least **2 mm** should be visible.





AVAILABLE IN 2 VERSIONS:

with anterior eyelet







with anterior hook







WITH ANTERIOR EYELET	WITH ANTERIOR HOOK	Туре	Length at full expansion (passive configuration)	Length at full compression (including 2 mm of additional compensation) see page 148	Maximum safety stroke of spring	Maximum opening allowed to prevent disassembly
M2302-00	M2301-00	EXTRA-SHORT	31 mm	25 mm	7,5 mm	48 mm*
M2302-01	M2301-01	SHORT	35 mm	28 mm	10 mm	56 mm*
M2302-02	M2301-02	LONG	40 mm	33 mm	10 mm	62 mm*

*Distance between the 2 eyelets or hooks of anchorage



M2301-91

CLASS II CORRECTOR KIT WITH ANTERIOR HOOK

Pack of **3 correctors** with anterior hook (1 extra-short, 1 short, 1 long) and 6 measuring gauges

M2302-91

CLASS II CORRECTOR KIT WITH ANTERIOR EYELET

Pack of **3 correctors** with anterior eyelet **(1 extra-short, 1 short, 1 long)** and 6 measuring gauges



With the help of this measuring gauge, it will be simple and intuitive to figure out which of the three available lengths will be the correct one.

ORTHODONTIC MINI IMPLANTS



SELF-DRILLING

The special design of the devices makes the insertion possible without the need of any pre drilling to prepare the implant site. The endosseous portion of the self-drilling mini implant features one apical portion (2 mm long) drill shaped in order to punch the bone and one threaded portion (1,75 mm in diameter and 6 mm long) with self-tapping coil for anchorage to the bone.



no osseointegration

made of stainless steel, easy removable



groove

for easy application of elastics and elastic chains

INFORMATION FOR DISTRIBUTORS OF ORTHODONTIC MINI IMPLANTS, "INTENDED USE", "RESPONSIBILITY", "SURVEILLANCE"

The 93/42EEC directive on medical devices is the official reference that dictates the regulations for marketing medical devices. The directive provides indications for all the phases of existence for the device (from the project phase through the traceability system, and surveillance), and it identifies all the characters who have to comply with the directive itself, which includes not only the manufactures, but also the distributors, the buyers, and even the users. As for the responsibilities of the single competence, Leone S.p.A. recommends to its direct clients, dental depots and exclusive dealers to follow and maintain the indications, warnings, and information for the univocal identification of the medical devices, as provided by the manufacturer on the labels, during all the marketing phases. With specific regard to Class IIB implantable products, all dental depots and exclusive dealers of Leone S.p.A. are required to keep records of the distribution of medical devices as of traceability available for verification, in case of need to trace back a product or its user in a univocal way.



self-drilling orthodontic mini implants

SELF-DRILLING ORTHODONTIC MINI IMPLANTS* WITH CLOSED DUAL SLOT



closed

The head of the mini implant is available in two transmucosal heights and has a **closed dual slot** for the application of wire and/or spring segments. The **closed dual slot** section is .018"x.025" and can accommodate round or rectangular wires. A minimal invasive surgical procedure is needed: in one phase, transmucosal with very good primary stability for immediate application of the orthodontic traction. Mini implants are supplied sterile, ready to use with the proper adapter for handpiece or with the screwdriver for hand insertion. Packs of 1



	Ø	←→	
	mm	mm	
 low head	- 1 <i>75</i>	8	002-1708-03
high head	1,75	8	002-1708-04



*Available only NON-sterile for the US market



080-1002-01 HANDPIECE ADAPTER FOR MINI IMPLANTS WITH CLOSED DUAL SLOT

For use with the handpiece for the insertion of self-drilling mini implants with closed dual slot also in difficult access areas.





080-1000-02 SCREWDRIVER FOR MINI IMPLANTS WITH CLOSED DUAL SLOT

080-1000-23 Refill tip



Courtesy of Drs. Nazario Russo and Giacomo Coppola

self-drilling orthodontic mini implants



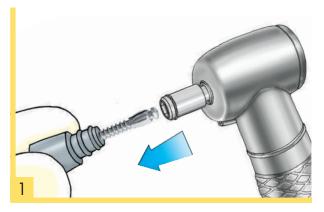
SELF-DRILLING ORTHODONTIC MINI IMPLANTS*

The head of the self-drilling mini implant is available in two transmucosal heights, it is mushroom shaped to facilitate the application of elastic ligatures and coil springs. One stage, transmucosal and minimal invasive surgical technique is needed, with optimal primary stability for the immediate load of the orthodontic appliance. Self-drilling mini implants are supplied sterile, ready to use with the special handpiece adapter. The use of a surgical micromotor is recommended. In case of use of a contra-angle utilized in the dental office, a complete implant insertion might not be obtained: the use of the Leone hand instruments, such as the ratchet Cat. 156-1014-00 or the fan-type hand wrench Cat. 156-1015-00 (page 154), may be necessary. Packs of 1

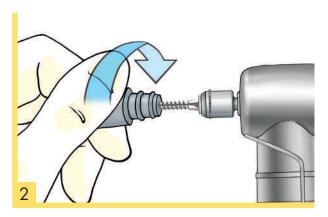
SELF-DRILLING ORTHODONTIC MINI IMPLANTS

		Ø	←→	
		mm	mm	
	low head	1 75	8	002-1708-01
	high head	1,75	8	002-1708-02

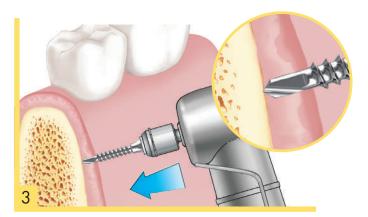
^{*}Available only NON-sterile for the US market



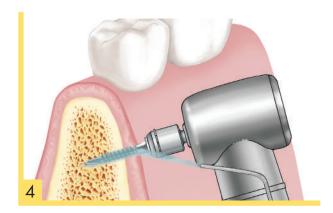
Remove the mini implant from the sterile vial by exerting a gentle traction on the implant cap and connect the handpiece adapter Cat. 080-1002-00 or 080-1002-01 to the head of the mini implant.



Once positioned into the adapter, remove the implant cap with a gentle counter clockwise rotary movement.



Lean the drilling tip of the mini implant on the attached mucosa in the selected area. Exert a pressure gentle enough to punch the soft tissues till the cortical bone has been reached.



Set the maximum speed on micromotor to 300 rpm and torque value to 40 Ncm. Start drilling the mini implant while irrigating abundantly with water. Immediately after having reached the cortical bone and as soon as the presence of a softer bone tissue has been detected, reduce the micromotor maximum speed to 50 rpm. Complete the insertion under these parameters.



The pictures and information described in this page have informative purpose only and they are not intended to furnish any therapeutic advice for the dental surgeon, the dentist, the dental technician or the patient.
Leone Spa expressly disclaims any liability neither will furnish any warranty regarding the exactness or the conformance of the information furnished in these pages.



self-tapping orthodontic mini implants



SELF-TAPPING ORTHODONTIC MINI IMPLANTS

Packs of 1

Made of stainless steel for surgical use and easily removable once the orthodontic movement has been achieved. They are available either with low or high head, in two types: one with a passing hole on the head and another with a groove and the protruding portion like an orthodontic button to facilitate the application of chains, elastics or springs. A clinical procedures leaflet for the positioning of the Orthodontic Mini Implants may be downloaded from our web site www.leone.it.

SELF-TAPPING ORTHODONTIC MINI IMPLANTS

		Ø	←→	
		mm	mm	
R			8	000-1508-02
	high head	1,5	10	000-1510-02
ATTENIA OF THE PERSON OF THE P			12	000-1512-02
Ñ			8	000-2008-02
	high head	2	10	000-2010-02
#	nedd	12		000-2012-02
9			8	000-1508-01
-	low head	1,5	10	000-1510-01
****			12	000-1512-01
	_		8	000-2008-01
	low head	2	10	000-2010-01
*			12	000-2012-01

ORTHODONTIC MINI IMPLANTS WITH GROOVE

		Ø	←→	
		mm	mm	
	high head		6	001-2006-02
		2	8	001-2008-02
			10	001-2010-02
*			12	001-2012-02
-20			6	001-2006-01
	low		8	001-2008-01
H	head	2	10	001-2010-01
			12	001-2012-01





001-0001-24 SELF-TAPPING MINI IMPLANT KIT

The package contains: 24 mini implants, 2 pieces each length and diameter available with low and high head, 4 drills, 1 screwdriver.

001-0002-24 SELF-TAPPING MINI IMPLANT WITH GROOVE KIT

The package contains: 24 mini implants with groove, 3 pieces each length available with low and high head, 2 drills, 1 screwdriver, 1 adapter Cat. 080-1003-00, 1 circular punch, 1 adapter Cat. 080-1002-00.

DRILLS FOR SELF-TAPPING MINI IMPLANTS

1.	Ø	←→	
	mm	mm	
	1,1		090-1134-00
W 24	1,3	_ 12	090-1334-00
¥	1,5		090-1534-00
B	1,7	_	090-1734-00

080-1000-01 SCREWDRIVER FOR SELF-TAPPING MINI IMPLANTS

080-1000-22 Refill tip

instruments for self-tapping orthodontic mini implants





080-1001-00 MUCOTOME FOR ORTHODONTIC MINI IMPIANTS

Circular scalpel to be attached to the handle of the screwdriver Leone Cat. 080-1000-01 for mini implants. With a diameter slightly larger than the head of the mini implants, the scalpel allows to prepare a suitable hole, without the need of any suture afterwards.



080-1001-01 CIRCULAR SCALPEL FOR CONTRA-ANGLE

Designed for the insertion of orthodontic mini implants. Made of titanium surgical grade. It is used with low speed contraangle allowing the creation of a suitable hole in the attached mucosa. Diameter 2,2 mm



080-1002-00 HANDPIECE ADAPTER

For use with the contra-angle for the insertion of mini implants also in difficult access areas.



080-1003-00 ADAPTER FOR SCREWDRIVER AND INSTRUMENTS

For use with screwdrivers Cat. 156-1001-00, Cat. 156-1001-01 and ratchet Cat. 156-1014-00 of the Leone Implant System in the application of mini implants in posterior or difficult access areas.



FAN-TYPE HAND WRENCH

Made of stainless steel and anodized aluminium. With hexagonal hole matching the mini implant's head. Sidewise it presents a hole for the insertion of a safety leash. It is necessary to complete the insertion of the mini implant into the implant site. Supplied non-sterile, sterilize under autoclave prior to initial use (part no. 156-1015-00 in the Catalogue of Leone Implant System).



lip bumper and extraoral facebows



M3052-00 MINI LIP BUMPER BY PROF. NICOLA VELTRI

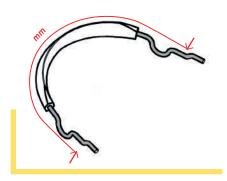
Designed by Prof. Nicola Veltri: this device is intended for use on patients with deciduous or mixed dentition with lack of space and/or small jaw with either sagittal or transversal dimension. The early application on deciduous molars positively stimulates the development of the mandible. The mini lip bumper is made with a special inclination of the archwire so as the anterior shield is positioned in the area where the lip is highly pushed forward and has a **stop adjustable screw** that makes a precise activation possible without the need of bending the wire. The adjustment of the stop requires the screwdriver P1520-00. Pack of 5



LIP BUMPER

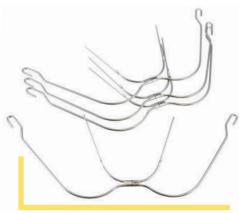
Made of biomedical stainless steel .045" wire. Non toxic techno-polymer labial coating.

M3050-00 without loops M3051-00 with loops



LIP BUMPER WITH LOOPS AND BAYONET STOPS

size	mm		pkg.		pkg.
1	76	M3051-01		M3051-011	
2	80	M3051-02		M3051-012	_
3	84	M3051-03	1	M3051-013	10
4	88	M3051-04		M3051-014	_
5	92	M3051-05		M3051-015	



EXTRAORAL FACEBOWS

Made entirely of biomedical spring stainless steel wire with single piece inner bow. Breakage resistant laser welded bow joint, with total absence of solder, to prevent from eventual allergic reactions due to the presence of two metals. Midline clearly marked. The outer bow is available in two lengths. Bright electro-polishing for maximum hygiene.

Caution: all extra oral facebows have to be used with Leone safety release modules M0810.



midline clearly marked

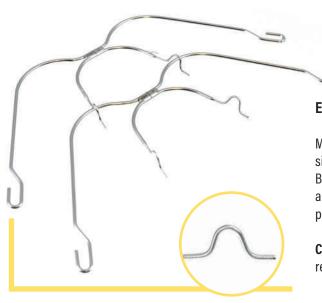


hooks for elastics

	outer arch diameter		er arch ameter		standar	d facebow				facebow for elastics	
	mm	mm	inch		pkg		pkg		pkg		pkg
long outer arch	— 1,80	1.14	.045	M4800-00	1	M4800-001	10	M4801-00	1 _	M4801-001	- 10
short outer arch	1,00	1,1-4	.043	M4830-00	·	M4830-001	10	M4831-00	•	M4831-001	10

extraoral facebows and accessories





EXTRAORAL FACEBOWS WITH PREFORMED LOOPS

Made entirely of biomedical stainless steel wire, 1,80 mm in diameter, with single piece inner bow, 1,14 mm (.045") in diameter.

Breakage resistant laser welded bow and bite joints, 0,5 mm thick, with total absence of solder, to prevent from eventual allergic reactions due to the presence of two metals. Bright electro-polishing for maximum hygiene.

Caution: all extraoral facebows have to be used with Leone safety spring release modules M0810.

WITH PREFORMED LOOPS

d = intermolar width from loop to loop in	millimeter		long outer bow				short outer bow			
		size		pkg.		pkg.		pkg.		pkg.
d	83	1	M4805-01		M4805-011		M4835-01		M4835-011	
<u>uosi</u>	90	2	M4805-02	_	M4805-021		M4835-02		M4835-021	
	97	3	M4805-03	1	M4805-031	10	M4835-03	1	M4835-031	10
	104	4	M4805-04	_	M4805-041		M4835-04		M4835-041	
U U	111	5	M4805-05	_	M4805-051		M4835-05		M4835-051	

WITH PREFORMED LOOPS AND HOOKS FOR ELASTICS

d = intermolar width from loop to loop in millime			long outer bow	
		size		pkg.
d	83	1	M4806-01	
uom 1	90	2	M4806-02	
	97	3	M4806-03	1
	104	4	M4806-04	
<u> </u>	111	5	M4806-05	



WITH PREFORMED LOOPS AND BITE

d = intermolar width from loop to loop in millime	eter		with bite plane hard stainless steel	
		size		pkg.
d	83	1	M4808-01	
	90	2	M4808-02	
	97	3	M4808-03	1
	104	4	M4808-04	_
II \	111	5	M4808-05	_

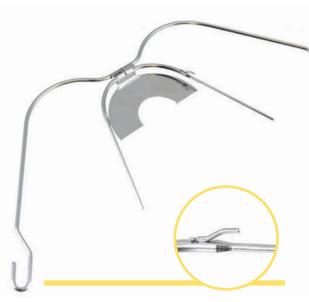
M3620-01

SLEEVE FOR EXTRAORAL FACEBOWS AND HEADGEARS

Pack of 10



extraoral facebows and accessories



EXTRAORAL FACEBOWS WITH SINGLE AND DOUBLE BITE

Made entirely of biomedical stainless steel wire, 1,80 mm in diameter, with single piece inner bow, 1,14 mm (.045") in diameter. Breakage resistant laser welded bow and bite joints, 0,5 mm thick, with total absence of solder, to prevent from eventual allergic reactions due to the presence of two metals. Bright electro-polishing for maximum hygiene.

Caution: all extraoral facebows have to be used with Leone safety release modules M0810.

	stan	dard	with hooks for elastics	with hooks and elastic retractor	
	with bite	with double bite	with bite	with bite	pkg.
hard stainless steel bite plane	M4808-00	M4824-00	M4809-00	M4807-00	,
soft stainless steel bite plane	M4808-10	M4824-10	M4809-10	M4807-10	· I
=					









M3307-00 WELDABLE STOP FOR ARCHES

Made of biomedical stainless steel. It is mostly used with intra oral arches and lip bumper. Just use a spot of a welding machine to fix it. For use with wire 1,14 mm (.045") in diameter. Pack of 10

M3714-00 WELDABLE

ADVANCEMENT BITE

Made of biomedical stainless steel. Its plain surface makes it to be welded to any stainless steel bite plane. Pack of 1

M3309-00

FACEBOW SCREW STOP

Made of stainless steel. For use with wire 1,14 mm (.045") in diameter. Pack of 10

M3309-95

FACEBOW SCREW STOP KIT

It includes: 50 stop screws and 1 screw-driver





FACE MASKS

REPLACEMENT

Used for treatment of maxillary insufficiencies, prognathism of the mandible and cleft palate. The reverse orthopaedic pull between maxilla and mandible facilitates the subsequent orthodontic treatment. Made of stainless steel wire and non toxic acrylic, it can be adaptable to perform any individual size requirement with vertical or horizontal adjustment. All attachments are locked by set screws in metal housings. Face masks with zygomatic holds feature an adjustable strap band.

Pack of 1

Packs of: 1 face mask, 1 screw wrench, instructions for use into a sleeve for patient

Chin pad

	PARTS	M0778-00 M0779-00	Forehead pad Zygomatic hold pad	Pack of 1 Pack of 2		
	BEIGE	RED	YELLOW	GREEN		_
	M0774-00	M0774-00R	M0774-00G	M0774-00V	SMALL	
WITH HORIZONTAL ADJUSTMENT	M0776-00	M0776-00R	M0776-00G	M0776-00V	LARGE	
	M0773-00	new-			MINI	

M0777-00







WITH M0774-01 SMALL
VERTICAL
ADJUSTMENT M0776-01 LARGE



WITH ZYGOMATIC HOLDS BEIGE

BEIGE

M0771-00



DYNAMIC FACE MASK

VERTICAL
ADJUSTMENT
M0772-01 M0772-01R

Packs of 1:

- 1 face mask,
- 1 adjusting wrench,
- 2 forehead pads,
- 2 chin pads and instructions for use

ELASTICS RECOMMENDED

		inner diameter	
		3/8" - 9,5 mm	1/2" - 12,7 mm
strong	8 oz - 224 g	K0935-08	K0936-08
extrastrong	14 oz - 392 g	K0945-14	K0946-14



extraoral headgear and safety headgear system



M0790-00 HEADGEAR WITH CHIN CAP

For correction of Class III malocclusions with prognathism of the mandible. Headgear and elastic tractions are fully adaptable; the chin cap in natural leather assures an ideal fit to any face. Colour: blue.

Pack of 1

REPLACEMENT PARTS

M0791-00 Chin pad Pack of 1

M0791-01 Elastics Pack of 2

small

medium

large



HEADGEAR FOR SAFETY MODULES

High pull. Use with safety release spring modules only. It fits onto safety hooks of spring modules. Made of 100% cotton, hypoallergenic and washable with comfortable padding. Available in 3 sizes and 2 colours to provide patient's psychological compliance. Packs of 1

	pink
small	M0805-00S
medium	M0805-10S
large	M0805-20S

M0805-00

M0805-10

M0805-20



NECK PAD FOR SAFETY MODULES

Low pull. Same as headgear both for use with safety modules and materials.

Available in 2 colours to provide patient's psycological compliance.

Packs of 10

MO800-00S Pink

M0800-00 Blue



For patient own face mask. Transparent coloured, washable, fully neutral coloured. Pack of 10







SAFETY RELEASE MODULES

For use with the suitable headgear or neck pads only. Safety clasps disengage the spring strap when a pressure pull of 2 Kg each side is exceeded. This system avoids dangerous slingshot rebound injuries of the facebow in case of disconnection from headgear tubes. Coil springs are incorporated

into the modules to provide constant traction force. Available in three colour-coded attachment straps showing the force level.

Packs of 10

	colour		
light	transparent	M0810-01	
medium	yellow	M0810-02	
heavy	blue	M0810-03	

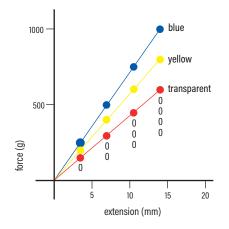


to indicate the different spring force of modules



clasps disengage the spring strap when a pressure pull of 2 Kg

each side is exceeded



Traction force released by each module can be easily controlled: when 2 notch tension appears on the plastic strap under traction, 2/4 (two fourths) out of the total deliverable force of the spring is going to be released. Above diagram shows the pull forces released by each type of module.