

TADs AND ORTHODONTIC MINI IMPLANTS





The mini implant series specially designed for the palatal anchorage of expanders

TAD INTEGRAL

made of medical grade 5 titanium



sterile packaging

vial cap with Titanium support for TAD

TAD

made of medical grade 5 titanium



sterile packaging

vial cap with Titanium support for TAD



self-drilling thread

ensures a simple surgical procedure and high primary stability.



NOT AVAILABLE IN US MARKET

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

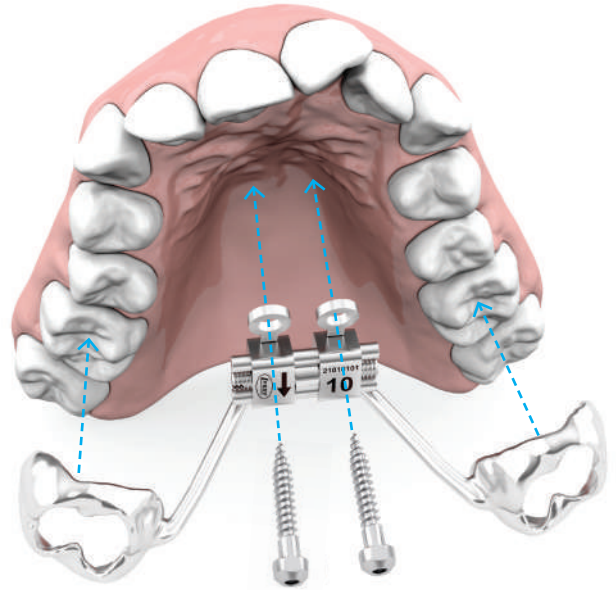
The 93/42EEC directive on medical devices is the official reference that dictates the regulations for marketing medical devices. The directive provides indications for all the phases of existence for the device (from the project phase through the traceability system, and surveillance), and it identifies 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.

TAD INTEGRAL

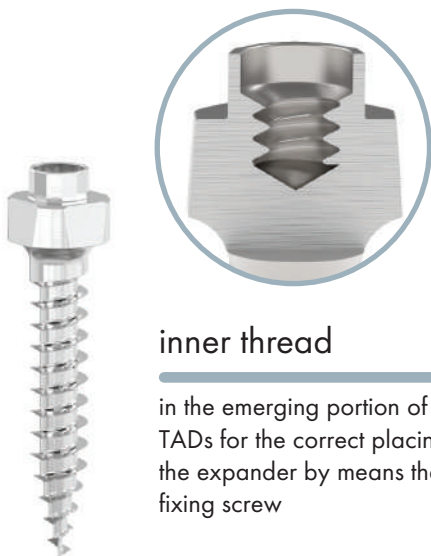


stopping head

thanks to the emerging portion, it is possible to insert both the appliance and the TADs during the same procedure

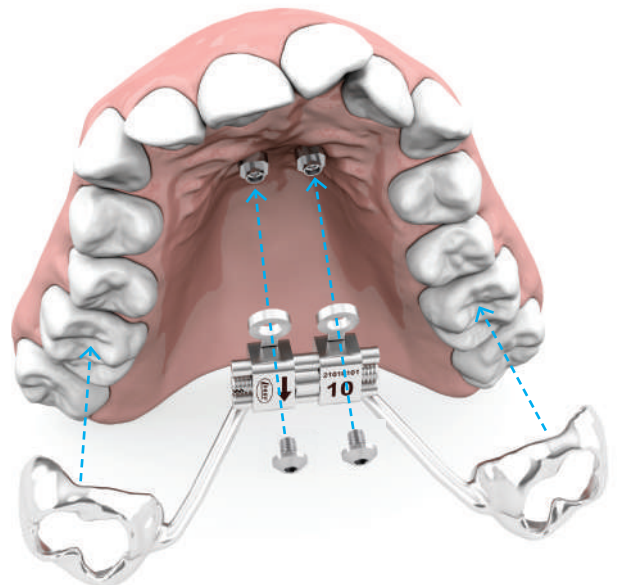


TAD



inner thread

in the emerging portion of the TADs for the correct placing of the expander by means the fixing screw



fixing screw

to ensure the correct anchorage of the expander

TAD INTEGRAL FOR EXPANDER

Leone TAD integral is a mini implant specially designed for the palatal anchorage of expanders during a single phase procedure, when both the appliance and the TADs are applied during the same visit.


The self-drilling tip and the peculiar shape of the TAD thread ensures a simple, minimally invasive surgical procedure and high primary stability.

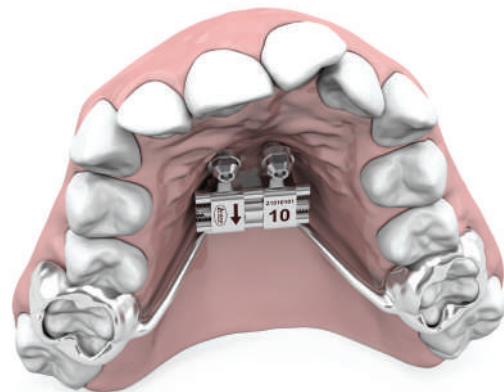
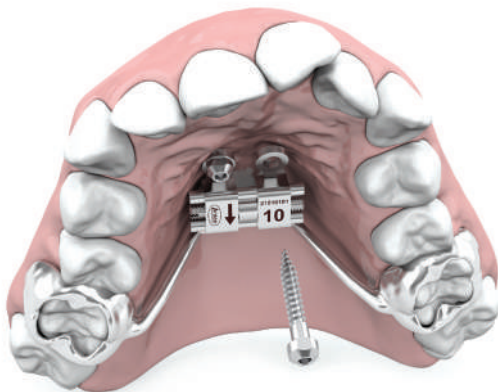
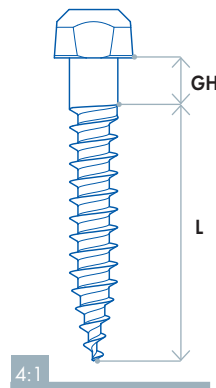
Made of Titanium grade 5, available in two lengths with \varnothing 2 mm, TADs are supplied sterile and ready to be used with the dedicated handpiece adapter (REF 083-1005-01 and 083-1006-01) or with the manual driver (REF 083-1007-01).

Pack of 1 or 2



new

	\varnothing	L		pkg.
	mm	mm		
	2	8	004-2008-10	1
			004-2008-20	2
	2	10	004-2010-10	1
			004-2010-20	2



TAD FOR EXPANDER

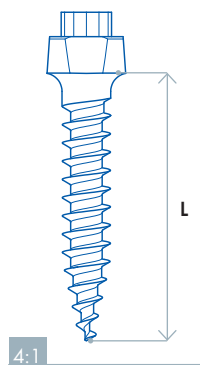


Leone TAD is a system specially designed for the palatal anchorage of palatal expander with a two-step procedure: the surgical procedure for the TADs application is followed by the impression taking, thanks to the impression accessories, that allows the lab realization and the application of the expander, both hybrid and totally Bone Borne. Made of Titanium grade 5, available in four length and with \varnothing 2 mm thanks to the peculiar shape of the TAD thread ensures a simple, mini-invasive surgical procedure and high primary stability. The emerging portion has an inner thread that, when coupled with the fixing screw, ensures a perfect anchorage with the palatal expander. Once the TADs are positioned in the most appropriate anatomical region and, thanks to the accessories for the impression taking, both conventional and digital, it will be possible to prepare a model with TADs analogs to fabricate the maxillary expander, with high precision and accuracy. TADs are supplied sterile and ready to be used with the dedicated handpiece adapter (REF 083-1005-01 and 083-1006-01) or with the manual driver (REF 083-1007-01).

Pack of 1 or 2

new

\varnothing	L		pkg.
mm	mm		
2	7	003-2007-10	1
		003-2007-20	2
2	9	003-2009-10	1
		003-2009-20	2
2	11	003-2011-10	1
		003-2011-20	2
2	13	003-2013-10	1
		003-2013-20	2



023-1702-20

2:1

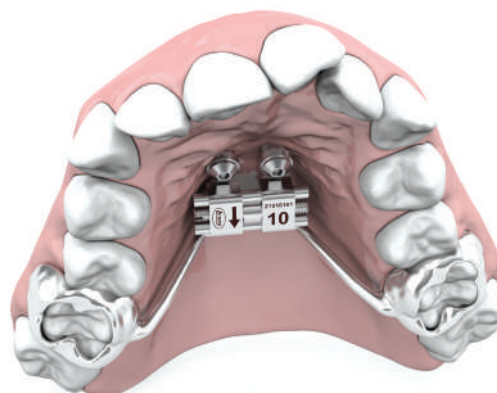
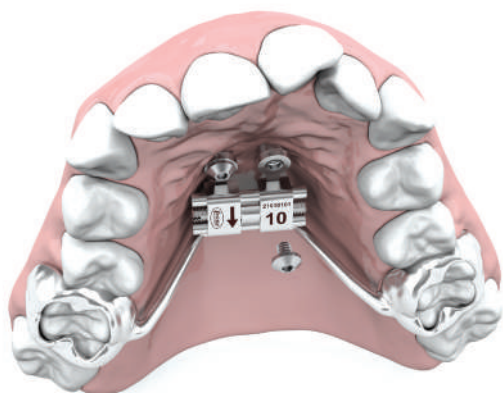
FIXING SCREW



033-3203-10 1 pc.
033-3203-20 2 pcs.

2:1

CYLINDER AND FIXING SCREW





1:1

083-1005-01 083-1006-01 HANDPIECE ADAPTERS FOR TAD

Both for TAD and TAD integral

Made of stainless steel.

Thanks to the centering system, the adapters allow the safe screwing and unscrewing the TADs with the con-trangled handpiece. Available in two lengths. Autoclavable.

Pack of 1



1:1

DRILL EXTENSION

Made of stainless steel.

In case of need, allows to increase the length of the drill and of the handpiece adapters. (REF 156-1019-00 in the Catalogue of Leone Implant System). Autoclavable.

Pack of 1



1:1

083-1007-01 MANUAL DRIVER FOR TAD

Both for TAD and TAD integral.

Made of stainless steel.

Thanks to the fan-type handle, allows to manually screw and unscrew the TADs. It can be also used by the lab for the analog positioning in the 3D-printed model. Autoclavable.

Pack of 1



2:1

043-0001-00 TRANSFER FOR TAD

Made of stainless steel, with a metallic threaded insert, thanks to the coupling with the inner thread of the emerging portion of the TAD, allows to determine accurately and with high precision the position of the TAD with a two material impression technique.

To be used with screwdrivers for fixing screw. Autoclavable.

Pack of 2



2:1

043-0000-35 SCAN BODY FOR TAD

Made of PEEK with a metallic insert, allows to obtain, with high precision and accuracy, the position of the TADs by means the intraoral optical impression or the scan of the dental cast.

To be used with the positioner for Scanbody REF 083-0004-00.

Autoclavable.

Pack of 2



1:1

083-0004-00 POSITIONER FOR SCAN BODY FOR TAD

Made of stainless steel, is used to screw and unscrew the Scanbody for TADs both on the TADs and on the analog for TAD. The top has a hole for the insertion of safety wire. Autoclavable.

Pack of 1



2:1

053-0001-00
ANALOG FOR TAD

Made of stainless steel to reproduce the position of the TADs in the dental cast or to be inserted in a 3D-printed model created by a digital impression.

Pack of 1



2:1

023-1702-20
FIXING SCREW

The fixing screw, made of Titanium grade 5, ensures the correct anchorage of the expander on the TAD. To be used with screwdrivers for fixing screw.

Pack of 2



2:1

033-3203-10 1 pc.
033-3203-20 2 pcs.
CYLINDER AND FIXING SCREW

Cylinder in stainless steel with an embedded screw, dedicated for the welding of expander arms or sintered metallic framework. To be used with the screwdrivers for fixing screw.

Pack of 1 or 2

L 12,5 mm



L 20 mm



1:1

083-0001-00 **083-0002-00**
SCREWDRIVERS FOR FIXING SCREW

Made of stainless steel, are used to screw and unscrew the fixing screws and the transfer for TAD.

Available in two length. Autoclavable.

Pack content:

- 1 screw adapter
- 1 hand screwdriver



1:1

083-0003-00
SCREWDRIVER FOR HANDPIECE FOR FIXING SCREW

Made of stainless steel, it is used to screw and unscrew the fixing screw and the transfer for TAD with the handpiece.

Use a max torque of 20 Ncm.

Autoclavable.

Pack content:

- 1 short screw adapter
- 1 handpiece adapter

070-8000-01

SURGICAL AND PROSTHETIC KIT FOR TAD

Made of PPSU plastic material, has been designed to sterilize and keep organized on the surgical field only the instruments necessary for the insertion of TADs and their prosthetics.

The cover when opened tilts the position of the kit and allows an easy access to instruments.

The kit is made up of 7 instruments (it can be filled up to 12):

- screwdriver for fixing screw short
- screwdriver for fixing screw long
- screwdriver for handpiece for fixing screw
- positioner for scan body for TAD
- manual driver for TAD
- handpieces adapter for TAD, short
- handpieces adapter for TAD, long

Entirely autoclavable.



070-0000-00

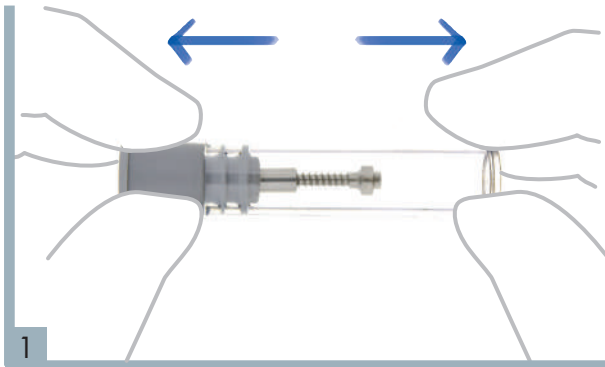
EMPTY KIT



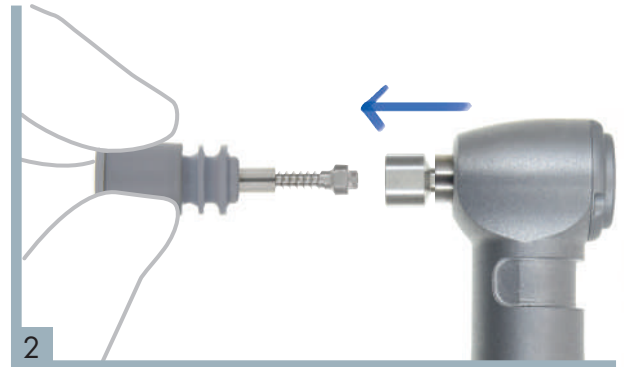
SURGICAL PROCEDURE

The design of the orthodontic appliance with bone anchorage, requires an accurate planning of the therapy by the clinician, who using his judgment, opinion and preparation, case by case, will consider also all the factors that might arise from pre-surgical exams as: anamnesis, objective exams, radiological, instrumental and laboratory investigations.

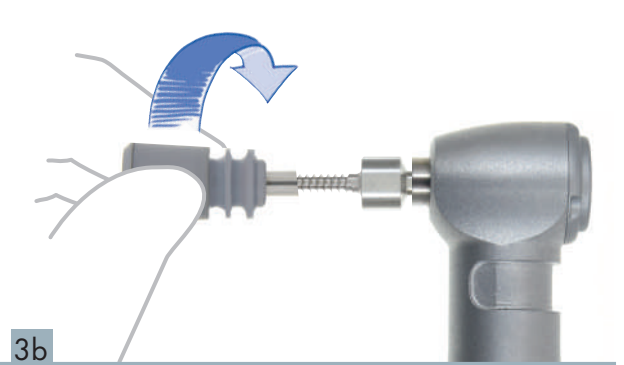
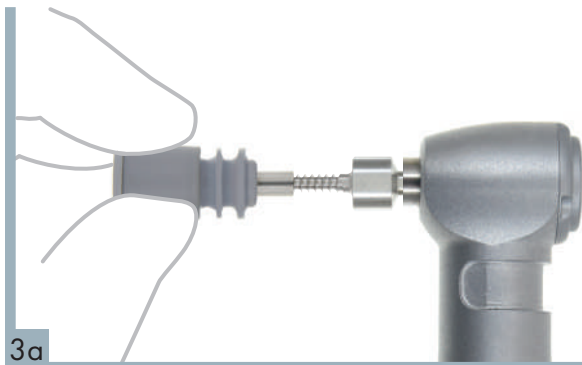
Once the surgical site and the more appropriate TADs have been determined, anesthetize the anatomical site. TADs are self-drilling, however in case of high bone density or thickness, it is suggested to drill the cortical bone with the drill for mini implants $\varnothing 1.5$ mm (REF 090-1534-00) to insert the TAD more easily.



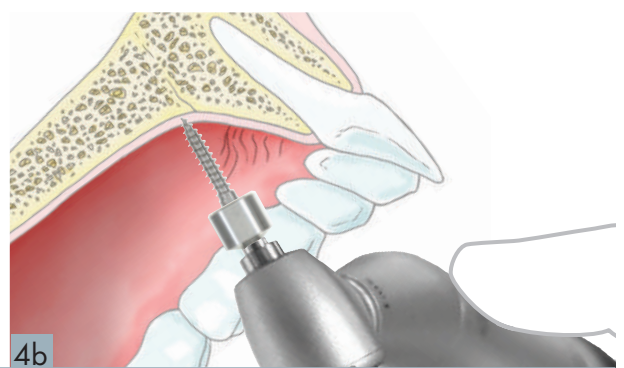
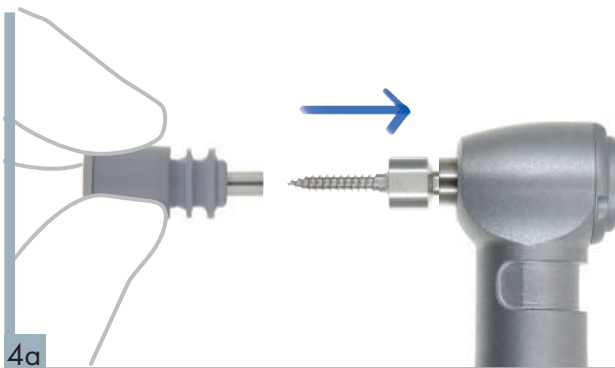
1 Exert a gentle traction on the vial cap, remove the TAD from the sterile vial.



2 Connect the dedicated handpiece adapter to the TAD head.

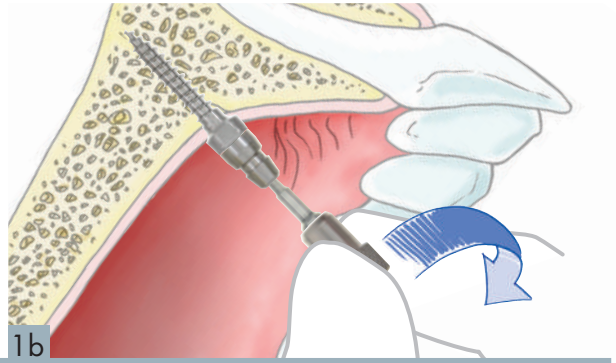
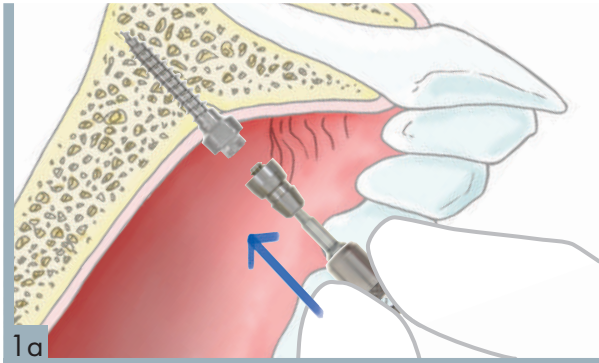


3a 3b Once positioned into the adapter, remove the implant cap with a gentle counter clockwise rotary movement.



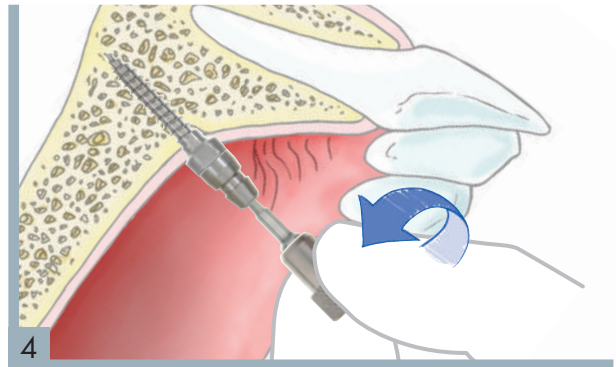
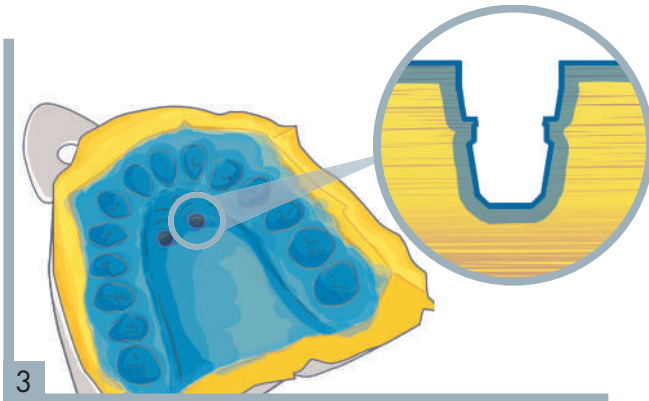
4a 4b Set a maximum speed of 30 rpm and a maximum torque of 30 Ncm, start drilling the TAD in the palatal vault.

CONVENTIONAL IMPRESSION TAKING



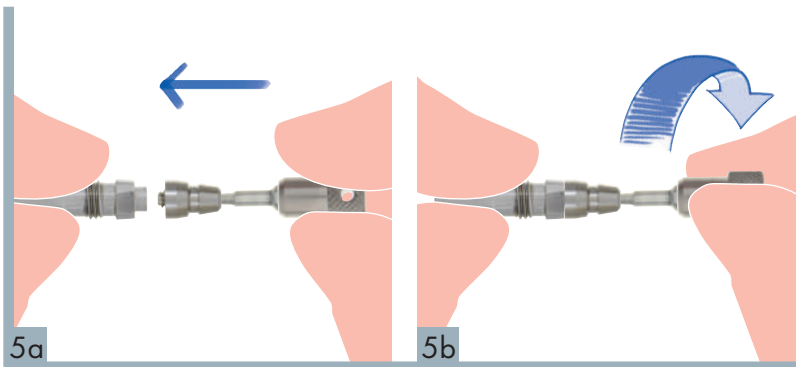
Screw the transfer in the emerging portion of the TAD using the dedicated screwdriver for fixing screw.

2 Take an impression with elastomeric material.

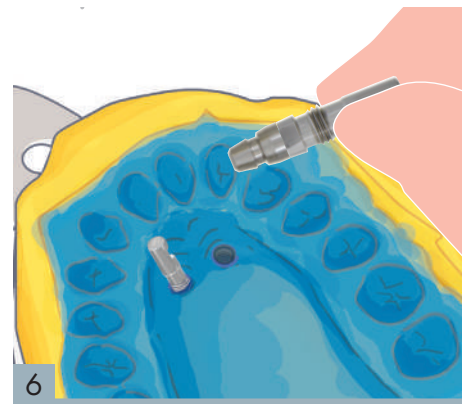


After the removal of the impression, the transfer remains on the TAD, while the negative reproduction of their shape is created in the impression material.

Unscrew the transfer using the screwdriver for fixing screw.

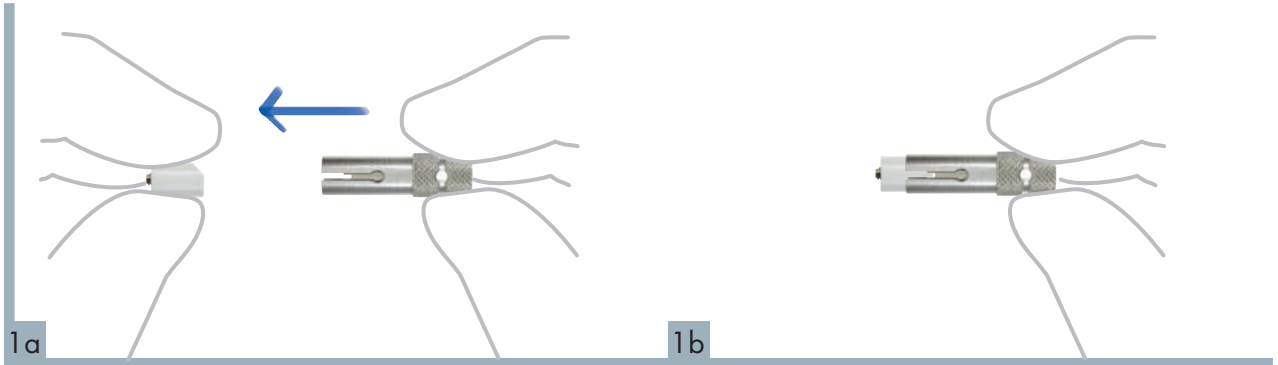


Screw the transfer on the analog.

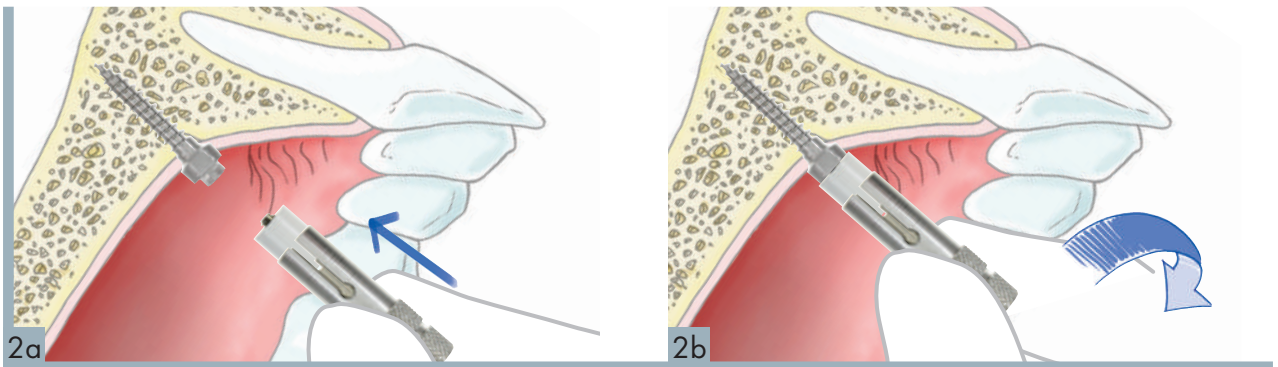


Replace the assembly analog+transfer into its seating in the impression. The specific shape of the transfer allows to easily perceive when a correct insertion is achieved.
Realize a dental cast where the analogs are embedded.

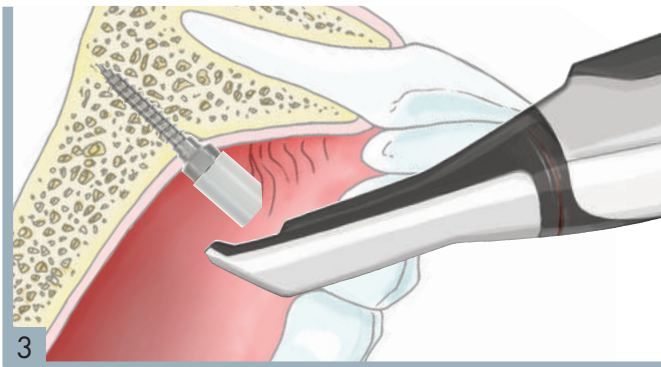
DIGITAL IMPRESSION TAKING



Insert the Scanbody in the dedicated positioner for Scanbody, ensuring the achievement of the perfect coupling.



Screw the Scanbody for TAD on the emerging portion of the TAD.

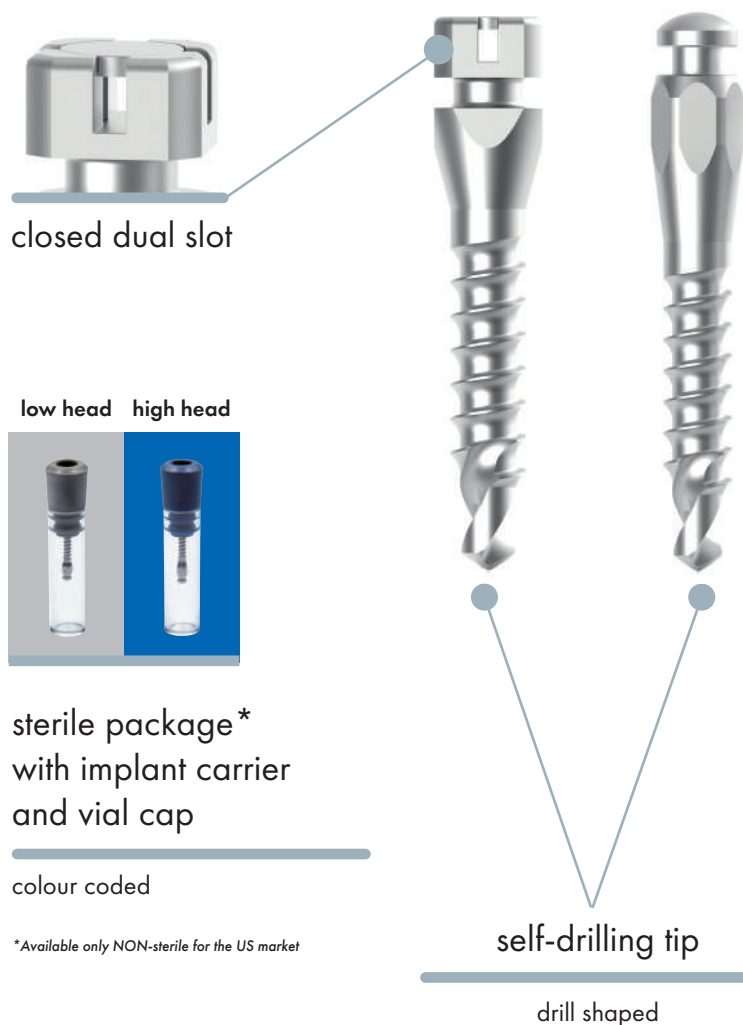


Take a digital impression to create a digital model.



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 surgical stainless steel,
easy removable



groove

for easy application of elastics
and elastic chains

sterile package*
with implant carrier
and vial cap

colour coded

*Available only NON-sterile for the US market

self-drilling tip

drill shaped

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 manufacturers, 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* WITH CLOSED DUAL SLOT

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 be used with the proper adapter for handpiece or with the screwdriver for hand insertion.

Pack of 1



	∅	L	
	mm	mm	
		8	002-1708-03
	1,75		
		8	002-1708-04

**Available only NON-sterile for the US market*

closed
dual slot



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*

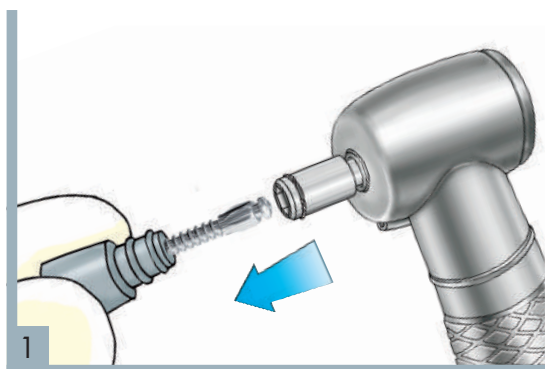
The head of the self-drilling mini implant is available in two transmucosal heights, it is mushroom shaped to facilitate the application of elastic ligatures and coil springs. One stage, transmucosal and minimal invasive surgical technique is needed, with optimal primary stability for the immediate load of the orthodontic appliance. Self-drilling mini implants are supplied sterile, ready to be used 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 REF 156-1014-00 or the fan-type hand wrench REF 156-1015-00 (page 186), may be necessary.

Pack of 1

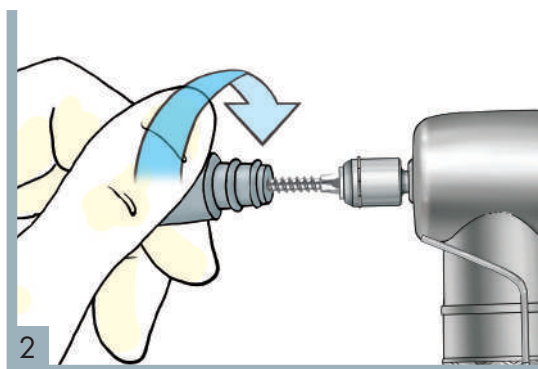
SELF-DRILLING ORTHODONTIC MINI IMPLANTS

		∅	L	
		mm	mm	
			8	002-1708-01
		1,75		
			8	002-1708-02

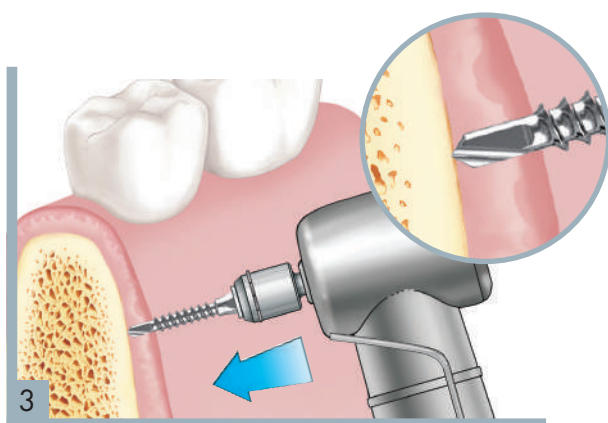
*Available only NON-sterile for the US market



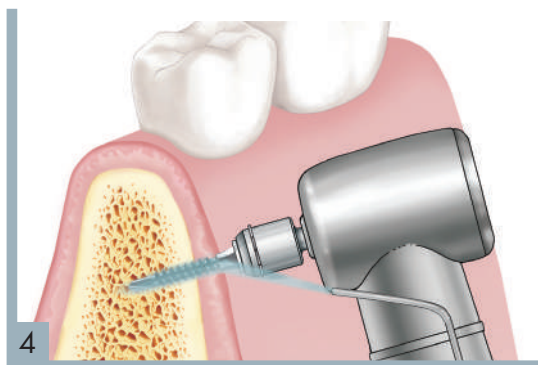
1 Remove the mini implant from the sterile vial by exerting a gentle traction on the implant cap and connect the handpiece adapter REF 080-1002-00 or 080-1002-01 to the head of the mini implant.



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



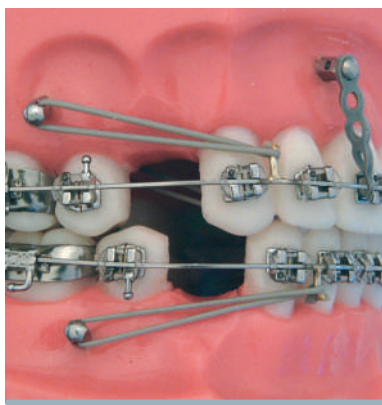
3 Lean the drilling tip of the mini implant on the attached mucosa in the selected area. Exert a pressure gentle enough to punch the soft tissues till the cortical bone has been reached.



4 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.



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SELF-TAPPING ORTHODONTIC MINI IMPLANTS

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.

Pack of 1

SELF-TAPPING ORTHODONTIC MINI IMPLANTS

		∅	L	
		mm	mm	
	high head	1,5	8	000-1508-02
			10	000-1510-02
			12	000-1512-02
	high head	2	8	000-2008-02
			10	000-2010-02
			12	000-2012-02
	low head	1,5	8	000-1508-01
			10	000-1510-01
			12	000-1512-01
	low head	2	8	000-2008-01
			10	000-2010-01
			12	000-2012-01

ORTHODONTIC MINI IMPLANTS WITH GROOVE

		∅	L	
		mm	mm	
	high head	2	6	001-2006-02
			8	001-2008-02
			10	001-2010-02
			12	001-2012-02
	low head	2	6	001-2006-01
			8	001-2008-01
			10	001-2010-01
			12	001-2012-01



001-0001-24 SELF-TAPPING MINI IMPLANT KIT

Pack content: 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

Pack content: 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

	∅		L	
	mm	mm	mm	
	1,1			090-1134-00
	1,3		12	090-1334-00
	1,5			090-1534-00
	1,7			090-1734-00

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

080-1000-22 Refill tip





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.



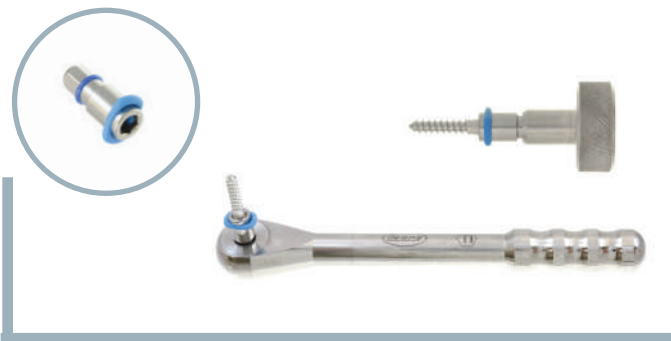
080-1001-01
CIRCULAR SCALPEL
FOR HANDPIECE

Designed for the insertion of orthodontic mini implants. Made of titanium surgical grade. It is used with low speed contra-angle 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 REF 156-1001-00, REF 156-1001-01 and ratchet REF 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 (REF 156-1015-00 in the Catalogue of Leone Implant System).