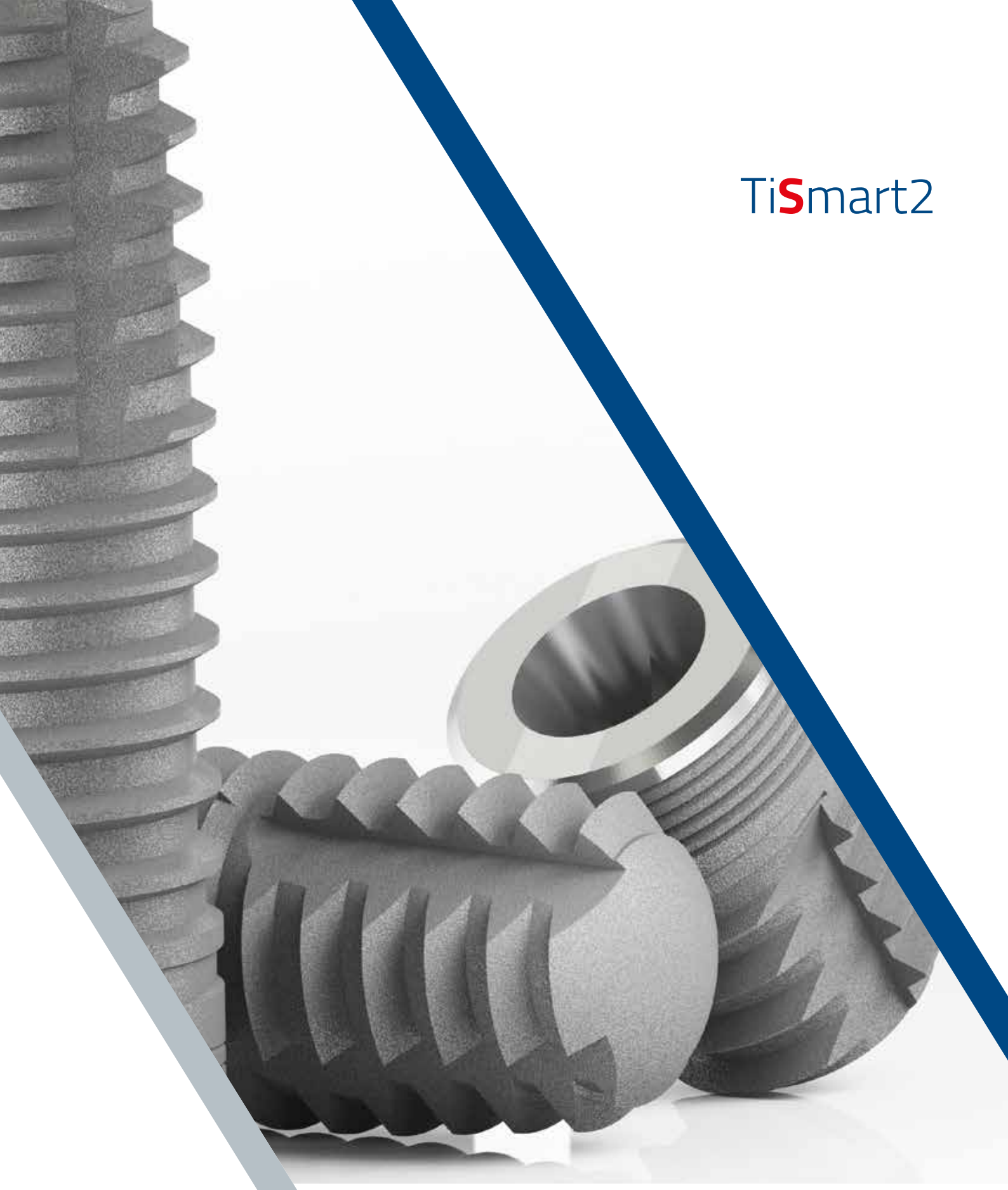
TiSmart2



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TiSmart2

MANUFACTURED FOR IMPLATECH

CONTENTS

THE COM

The company was founded in 1995 and is based in Padua. In collaboration with Academics and private sector professionals, the company designs, produces and trades titanium medical products under its own registered brand in the fields of Orthopedics, Maxillofacial Surgery, Neurosurgery and Implant Dentistry, which is the true core of the business.

All production processes are carried out at the Company, from the raw materials to the manufacturing and packaging that takes place in the cleanroom.

Leader Medica has always been attentive to the Patient's needs and that is why they have adopted raw materials and industrial procedures that exclude the presence of Aluminum in the finished product to avoid interactions with the body.

The presence in international markets and the close collaboration with medical specialists have shown that Leader Medica is a player and a leading company for those professionals who want to provide their patients with certified and guaranteed materials.

MPANY

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PRODUCT

The entire production process of the TiSmart2 implant is managed at the production site of Leader Medica, based in Padua.

The different operational phases are all planned and managed at the company, which guarantees their quality and standardization. In particular, the process includes the following phases:

1) Design, 3D simulation, F.E.M. simulation and prototyping

2) Technical tests of resistance and functionality carried out in collaboration with the Department of Mechanical Engineering at Polytechnic University of Milan

3) Production of the implants and their prosthetic parts by using CNC precision lathes and performing dimensional checks of all produced parts, including prosthetic parts

4) Acid-etched process for getting perfect superficial roughness

5) Decontamination by a cold plasma reactor using a mixture of argon and nitrogen

6) Electronic microscope checks carried out in collaboration with the Engineering Department at the University of Padua

7) Sterilization by means of Beta Rays at a specialized and certified laboratory

8) Packaging and storage

The UNI EN 13485:2016 certification of the entire production process obtained from independent certifying agencies, confirms the qualitative superiority of Leader Medica products.

TION

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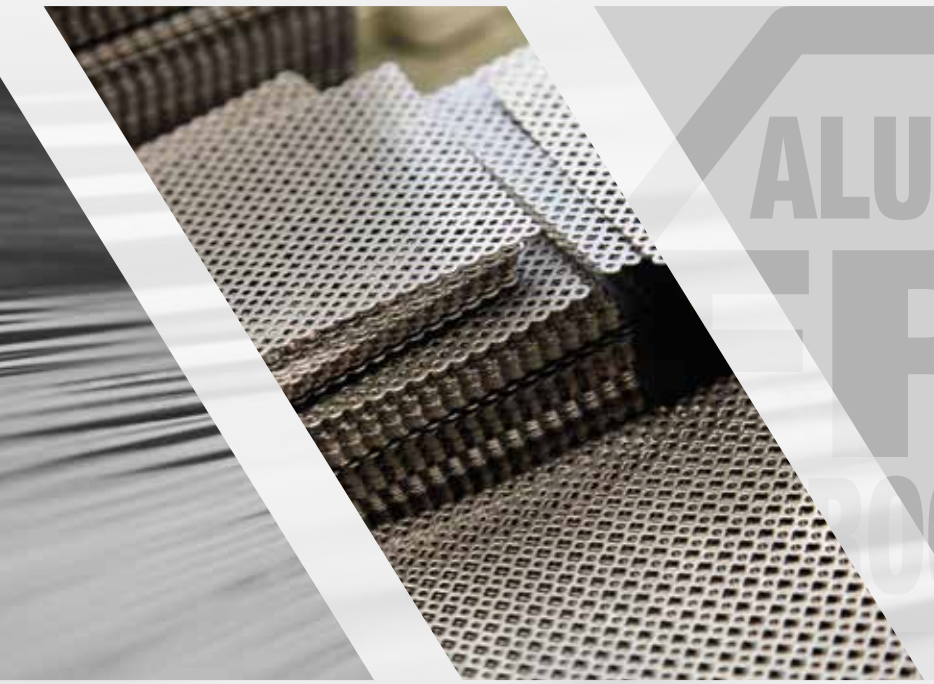
RAW MAT

Leader Medica has always been careful to select the best raw materials in the market. Titanium is purchased from certified suppliers that guarantee both its provenance and working in Germany and the United States. All received materials are inspected again at the company to make sure that they correspond to high production standards. Implants are made of cold worked Grade 4 Titanium (99% pure); this special working guarantees its high mechanical resistance. Moreover, the Leader Medica research laboratory has developed an industrial Aluminum Free Processing which ensures that even traces of aluminum are not present on any part of the implant's surface. This is a further guarantee for patients since aluminum is not biocompatible and is actually toxic to the body.

TERIALS



ALUMINIUM
FREE
PROCESSING

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IMPLANTS

The Bone Level TiSmart2 System is made in Titanium 99%.
There are four available diameters: 3.4, 3.75, 4.5, 5.0, with lengths varying from 7 mm to 15 mm.
The implant body is cylindrical at the coronal area, conical in the center and apex. This shape helps the surgeon to correctly manage the intraradicular bone spaces and guarantees the best possible primary stability[1-4].

The D.S.A. connection (Double Seal Action) is at double geometry: the coronal area is conical with an 11-degree angle which guides the insertion of the transfer and abutment, increasing the bacterial seal9. The internal section is hexagonal and stabilizes the abutment and helps reposition the prosthesis at 60° intervals.
The constant size of the internal hexagon enables "Platform Switching". As the implant diameter increases, it changes from a switch of 0.30 mm, for an implant diameter Ø 3.4 mm, to 1.10 mm for diameters larger than Ø 5.0 mm, which assures lower bone reabsorption and helps maintain the peri-implant soft tissue[10-17], to the benefit of the long term aesthetic result[18-21].

The variable geometry spirals enable modulating the implant primary stability during insertion, in all bone hardness conditions[22-26]. The micro-threading on the coronal area reduces bone reabsorption[27-32] and therefore improves the long-term performance.
The apical incisions (from three to four depending on the implant diameter and length) mean the implant is self-taping and easy to insert, and also guarantees excellent anti-rotation effect.

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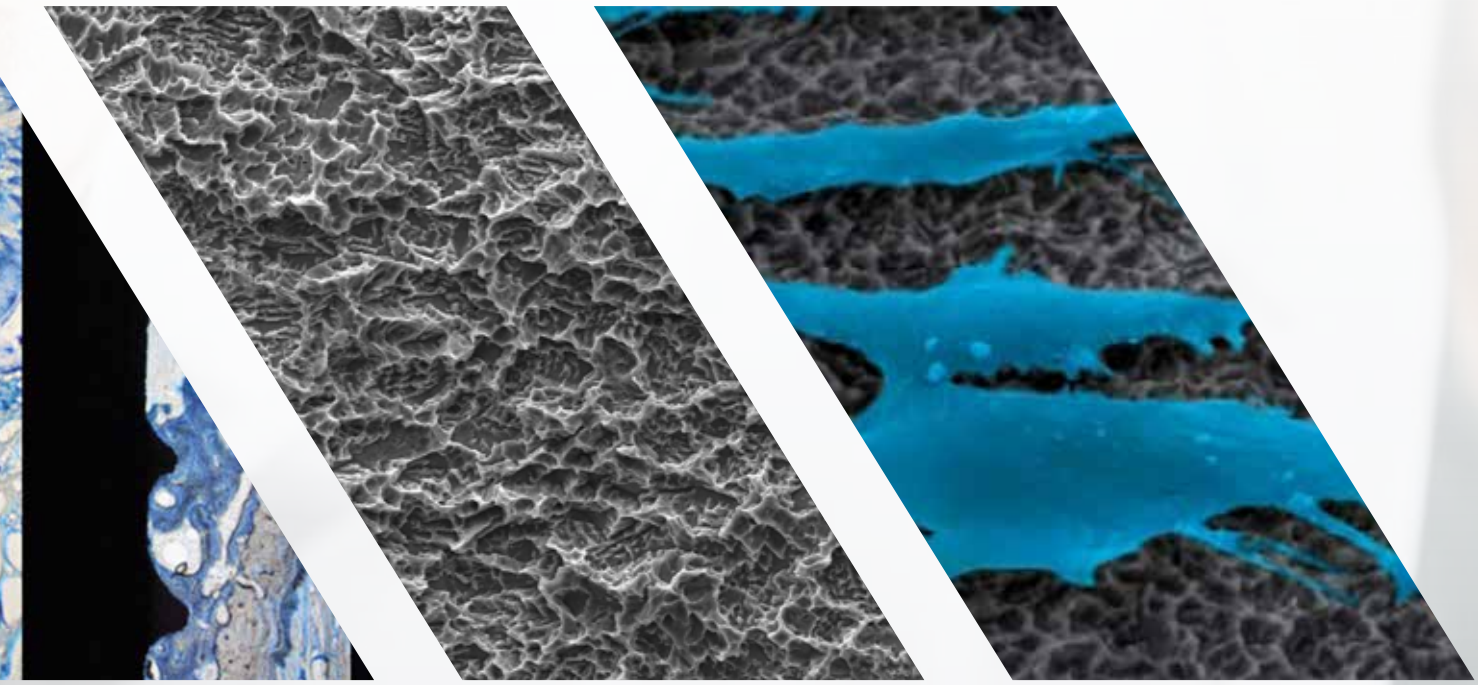
SURFACE

All of Leader Medica's implant lines are made with a double acid-etched process that eliminates "sandblasting," a possible source of aluminum contamination. This treatment is extensively documented in international literature and allows for a superficial roughness of Ra=1.3 µm, which is considered excellent in the activation of cellular differentiation processes. High BIC values on the surface allow for faster applications of the TiSmart2 implants in the mandible and jaw.

The chemical and physical analyses carried out in each production batch prove that the entire implant surface is free of aluminum, even traces of it, and comply with Aluminum Free Processing.



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DSA connection

The Double Seal Action is at double geometry: the coronal area is conical with an 11-degree angle and lets the proper insertion of the prothesis while also guaranteeing the best bacterial seal between the abutment and the implant[9]. The inner part is hexagonal and is used to stabilize the abutment and position the prosthesis at 60° degrees intervals.

Platform switching

The constant size of the connection for all diameters makes it possible for the prothesis switch from 0.3 mm to 1.1 mm according to the implant diameter in order to allow less peri-implant bone resorption and consequently the maintenance of soft tissues[10-27] for improving the aesthetic performance over the long period[18-21].

Coronal morphology

Machined in the first 0.5 mm and constant pitch microthread, which reduces bone resorption[27-32] and the accumulation of plaque.

Thread

Different depth and constant pitch, the apical threads are 0.1. mm deeper and provide a larger contact surface between the bone and the implant. The threads angle is 30°.

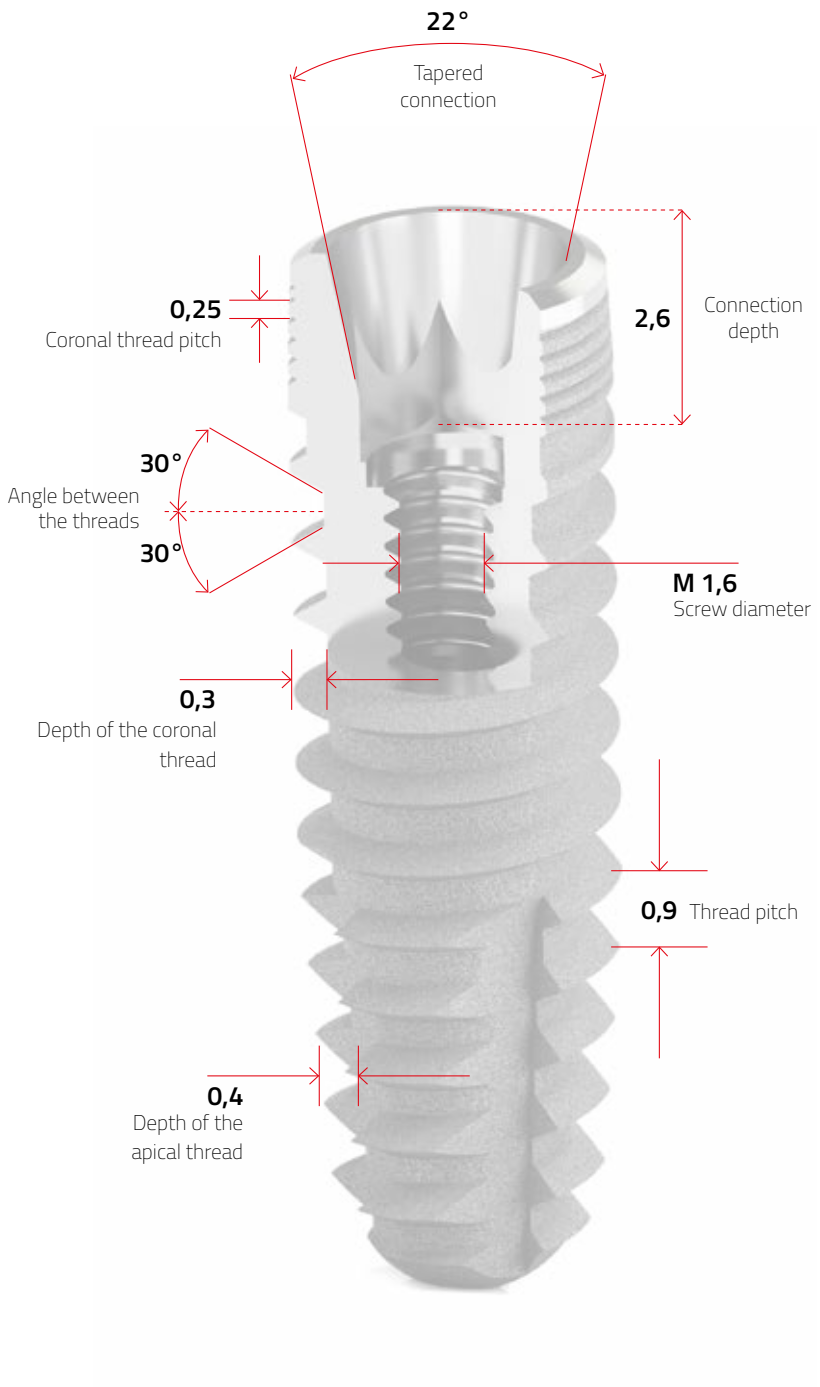
Apical incisions

Three or four incisions, depending on the diameter and the height of the implant, make the implant "self tapping" and facilitate its insertion. They also have excellent anti-rotation features.

Apex

Rounded to protect the critical anatomic structures, such as the mandibular nerve or the Schneiderian membrane.

TECHNICAL FEATURES OF THE IMPLANT



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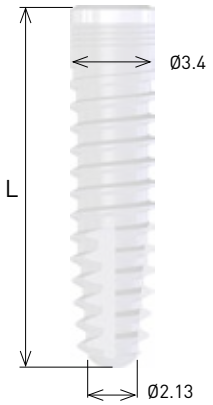


Ø3.4

ALUMINIUM FREE PROCESSING

Titanium 99%

	code	L [mm]
	**TTI3485**	8,5
	**TTI3410**	10
	**TTI3411**	11,5

	code	L [mm]
	**TTI3413**	13
	**TTI3415**	15

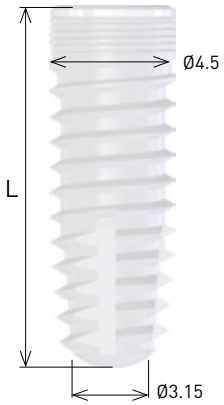
Ø3.75

ALUMINIUM FREE PROCESSING

Titanium 99%

	code	L [mm]
	**TTI3785**	8,5
	**TTI3710**	10
	**TTI3711**	11,5

	code	L [mm]
	**TTI3713**	13
	**TTI3715**	15



Ø4.5

ALUMINIUM FREE PROCESSING

Titanium 99%

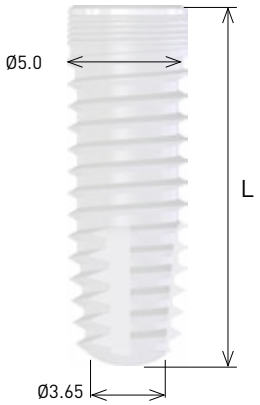
	code	L [mm]
	**TTI4585**	8,5
	**TTI4510**	10

	code	L [mm]
	**TTI4511**	11,5
	**TTI4513**	13
	**TTI4515**	15

Ø5.0

ALUMINIUM FREE PROCESSING

Titanium 99%



	code	L [mm]
	**TTI5007**	7
	**TTI5085**	8,5
	**TTI5010**	10

	code	L [mm]
	**TTI5011**	11,5
	**TTI5013**	13
	**TTI5015**	15

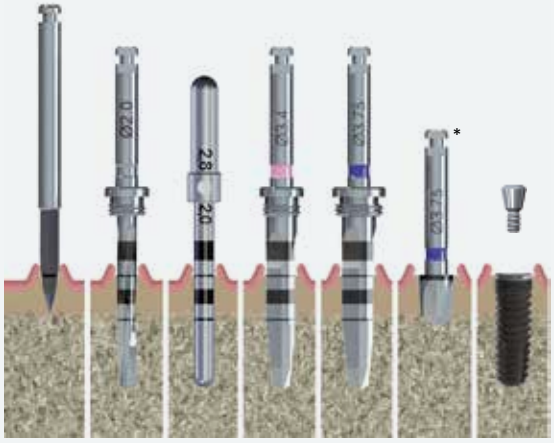
SURGICAL PR

Drilling Speed (RPM) 800 800 200-400 200 15-25
Diameter Ø 2,0 Ø 2,0 Ø 3,4 Ø 3,4

Ø3.4

Drilling Speed (RPM) 800 800 200-400 200-400 200 15-25
Diameter Ø 2,0 Ø 2,0 Ø 3,4 Ø 3,75 Ø 3,75

Ø3.75



Do not use the final drill for bone types D3 and D4.
The drilling sequence is demonstrated with a 11,5mm implant.
*In case of D1 bone, cortical drill is recommended.
Implant recommended insertion torque 40-50 N*cm
Short drills without stop are available.

ROTOCOLS

Drilling Speed (RPM)	800	800	200-400	200-400	200-400	200	15-25
Diameter	Ø 2,0	Ø 2,0	Ø 3,4	Ø 3,75	Ø 4,5	Ø 4,5	

Ø4.5

Drilling Speed (RPM)	800	800	200-400	200-400	200-400	200-400	200	15-25
Diameter	Ø 2,0	Ø 2,0	Ø 3,4	Ø 3,75	Ø 4,5	Ø 5,0	Ø 5,0	

Ø5.0

Do not use the final drill for bone types D3 and D4.
The drilling sequence is demonstrated with a 11,5mm implant.
*In case of D1 bone, cortical drill is recommended.
Implant recommended insertion torque 40-50 N*cm
Short drill without stop are available.

PACKAGI

The TiSmart2 implants, Cold Plasma de-contaminated, are packed in the clean room under a laminar flow hood and then sterilized by Beta Rays.

The implant is kept in a colored titanium O-ring that identifies the diameter and facilitates its removal, avoiding contact with the plastic vial walls. The cap screw on the vial bottom can be easily removed by gently pressing the screwdriver whose conical tip "locks" the screw.

TiSmart2 implants are Mountless designed.

The implant is picked up by the practical friction-cone coupling device both manual and for contra-angle that makes implant removal easy after inserting it in the site.

Traditional systems equipped with a mounter need screwdrivers and wrenches that are often difficult to use, especially in reduced mesial/molar spaces or with difficult patients.

NG

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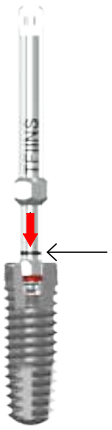
The TiSmart2 System is packed inside a thin carboard box with a transparent window that allows one to verify, thanks to the color code, the diameter of the implant. The practical tear off strip facilitates the removal of the blister that contains the sterile vial. Inside, there are the adhesive stickers to put on the patient's chart and on the implant passport to be delivered to the patient. The passport gives the batch number as well as the diameter and the height of the inserted implant. The package also contains an instructional leaflet with photos that show how to safely remove the implant from the sterile vial.

(cod. TFIINS)

(cod. TFIDR)



(fig. 1)

IMPLANT REMOVAL

Remove the top cap. Press slightly on the connection to extract the implant from the vial. Two methods can be used: with the contra-angle accessory (code TFIINS) or with the manual accessory (code TFIDR).

The reference notch, indicated by the **red arrow**, must be completely inside the connection (fig. 1).

REMOVAL OF THE CAP SCREW

Remove the bottom cap. Extract the cap screw by pressing the TDR12C screwdriver into the connection and unscrewing by hand with a recommended torque of 15 N*cm.

SURGICA

The TiSmart2 surgical kit is made of Radel®, a plastic material suitable to harmlessly undergo a number of sterilization cycles and not generate oxidizing currents among the different metal components of the kit.

The use of permanent retaining O-rings eliminates the accumulation of blood residuals and organic contaminants that are usually found, even after a proper washing, in "old generation" surgical kits.

The TiSmart2 surgical kit complies with the Best Practice regulations in the sterilization field.

The color code identifies the surgical sequence and the relevant implant diameters.

Laser marking of all components and the relevant serigraphy on the housing hole allow for easy identification when returning the components back to the kit.

The TiSmart2 system provides straight flute drills that allow for the best directionality. Their design is suitable to collect the bone produced during corticotomy. The drills are equipped with a screwable stop to protect the most delicate anatomical structures at the most risk during all surgical phases[38-43].

L KIT

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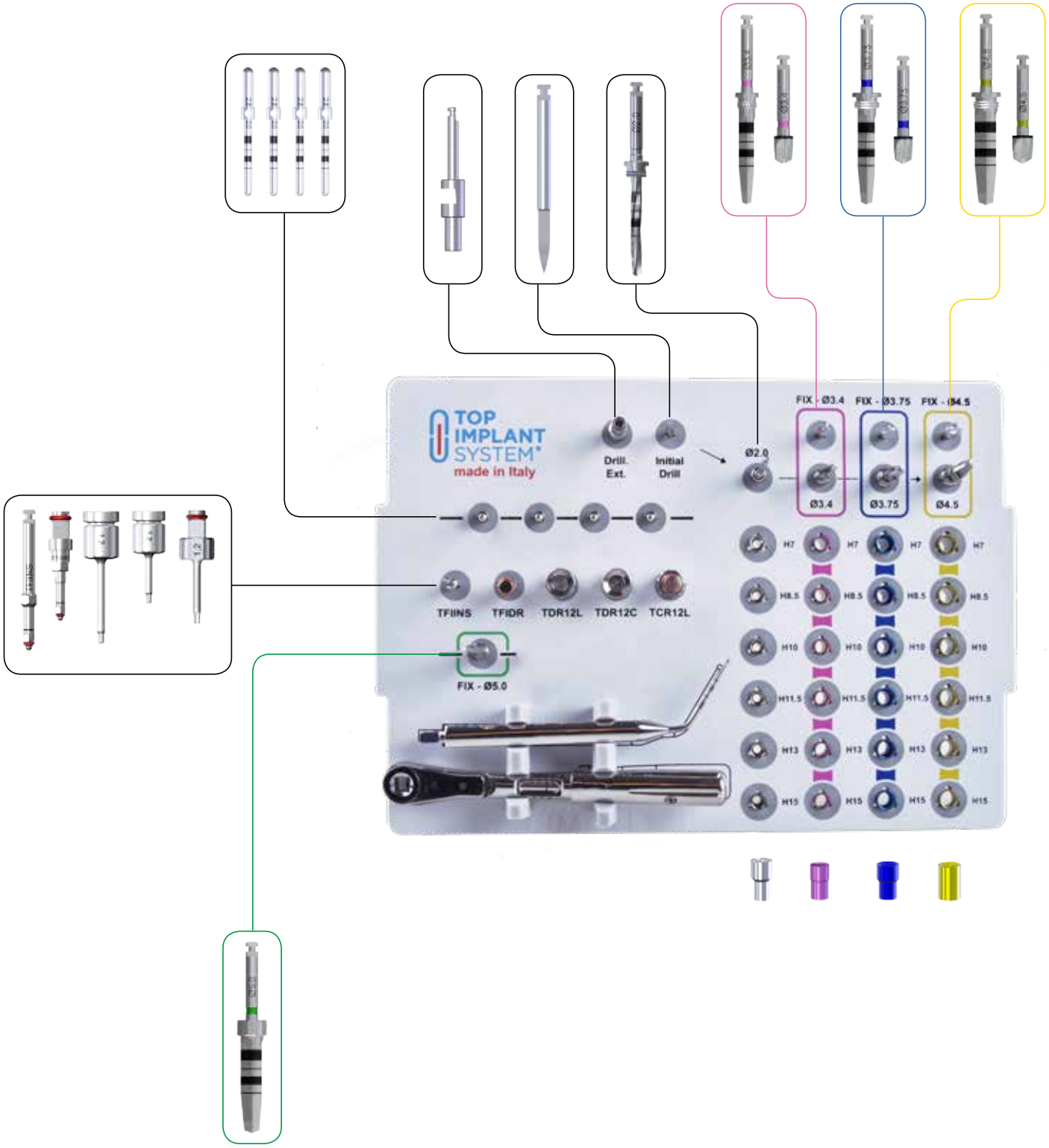
Accessory arrangement



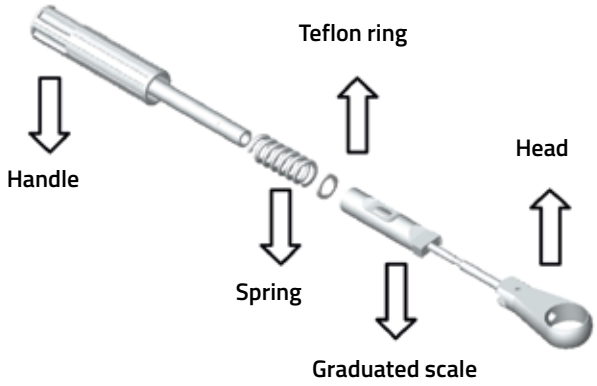
Wash:
Immerse the drills and the surgical accessories in a solution of water and specific cleaner. Leave for a few minutes before rinsing them properly with water and removing all residuals with a soft brush. Immerse the tools in an ultrasonic bath with an enzymatic cleaner for 5 minutes and pay attention that the mill blades don't touch one another. Then rub the tools with a soft brush and rinse properly with water. Check that everything is properly cleaned. The surgical tray must be washed, brushed and rinsed with water and some cleaner to eliminate any organic residuals.

Sterilization:
Immerse the drills and the surgical accessories in a solution of water and specific cleaner. Leave for a few minutes before rinsing them properly with water and removing all residuals with a soft brush. Immerse the tools in an ultrasonic bath with an enzymatic cleaner for 5 minutes and pay attention that the mill blades don't touch one another. Then rub the tools with a soft brush and rinse properly with water. Check that everything is properly cleaned. The surgical tray must be washed, brushed and rinsed with water and some cleaner to eliminate any organic residuals.

Maintenance of the ratchet:
All tools must be cleaned (ultrasound equipment is recommended) and sterilized before use according to the UNI EN 556-1:2002 regulation. Use oil suitable for contra-angles/micromotors to lubricate the threads internally. Clean and sterilize using specific materials and avoid cleaners containing the following:
- Oxalic acid
- Highly-concentrated chlorine
- Sodium hypochlorite

Immediately after a surgical operation, insert the tools in the disinfecting solution to prevent the incrustation of blood and other organic residuals.
Do not return a tool back if it is wet. Do not sterilize or clean or disinfect tools made of different metals in the same cleaning cycle.

Unscrew the handle and pay special attention not to lose the Teflon ring.
Remove the graduated scale and the spring inserted in the handle.
Clean each part of the device and make sure that the spring turns are properly cleaned.
Reassemble the device by inserting the components as given: insert the spring in the handle, insert the Teflon ring, screw the handle with the head of the wrench and insert the graduated scale between the two parts.



DRILLS

The drills of the TiSmart2 system are designed, produced and sharpened at Leader Medica. They ensure higher cut precision and longer duration (up to 50 cycles of use) compared to other drills in the market. The "straight blade" design provides a higher precision of cutting and control. Along the blade, it is possible to collect the bone produced during a corticotomy that can later be useful for a regeneration surgery or in post-extraction sites. The drills are made in 630 AISI steel and equipped with screwable colored stops made in Grade 5 titanium. All drills have a color code, diameter and code marked with laser. The height notches start from 7 mm and go to 15 mm to meet all available implants. The notch marking does not consider the tip length which adds a length up to 1.4 mm in the 5.0 mm diameter drill.

(See fig. 1 page 35).

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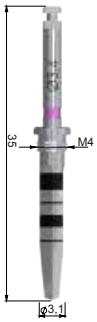
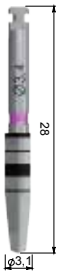
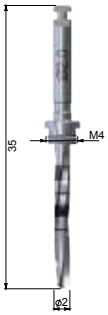
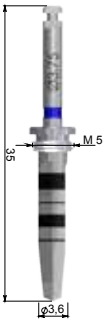
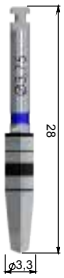
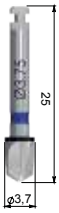
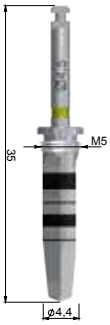
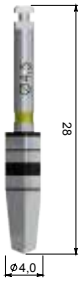
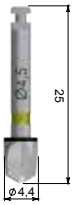
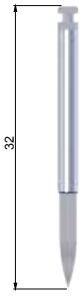
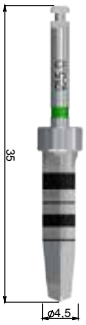
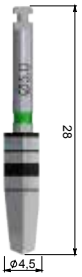
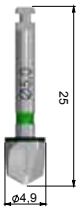
	code	Ø [mm]	description
	**TTIFR34**	3,4	Conical drill
	**TTIFR34SH**	3,4	Short conical drill (Not included on Kit)
	**TTIFRC34**	3,4	Cortical drill
	**TSTOPC34XX**		Stop
	**TFR20**	2,0	Cylindric drill

	code	Ø [mm]	description
	**TTIFR37**	3,75	Conical drill
	**TTIFR37SH**	3,75	Short conical drill (Not included on Kit)
	**TTIFRC37**	3,75	Cortical drill
	**TSTOPC37XX**		Stop
	**TFR20SH**	2,0	Short cylindric drill (Not included on Kit)

	code	Ø [mm]	description
	**TTIFR45**	4,5	Conical drill
	**TTIFR45SH**	4,5	Short conical drill (Not included on Kit)
	**TTIFRC45**	4,5	Cortical drill
	**TSTOPC45XX**		Stop
	**TFRLANC**		Spade drill

	code	Ø [mm]	description
	**TTIFR50**	5,0	Conical drill
	**TTIFR50SH**	5,0	Short conical drill (Not included on Kit)
	**TTIFRC50**	5,0	Cortical drill (Not included on Kit)
	**TSTOPC20XX**		Stop

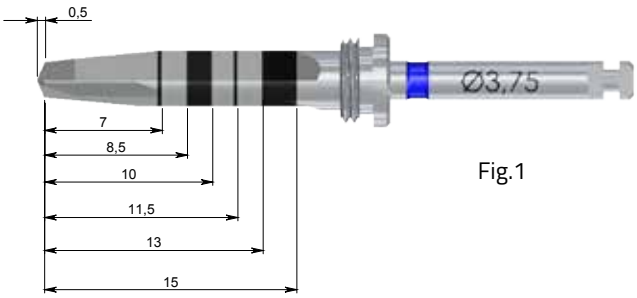


Fig.1

ACCESSO

The TiSmart2 Kit surgical accessories are designed to provide the surgeon with all the essential tools needed to use the TiSmart2 implants in any surgical condition. Drivers are available to extract and insert both manual and contra-angle implants of different heights, screwdrivers all having the same size of the hexagon (1.2 mm) suitable both for a ratchet connection and a manual operation with two different heights and a dynamometric ratchet suitable for checking the correct torque for inserting the implant and abutment screws. The accessories are made of AISI 420 steel and keep their connection precision for several work cycles if they are used within the recommended torque.

ORIES

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code	descrizione
	**TFIDR** Ratchet driver
	**TDR12C** Short manual screwdriver
	**TCR12L** Ratchet screwdriver
	**TPRFR** Drill extension

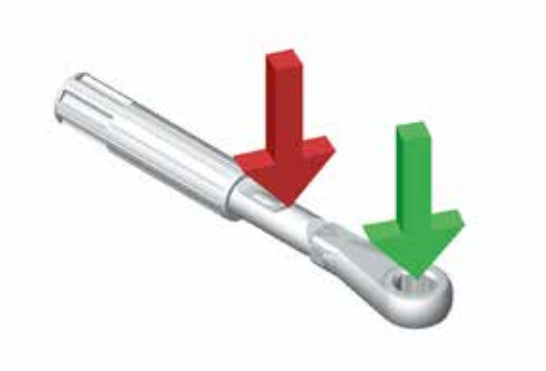
code	description
	**TFIINS** Contra-angle driver
	**TDR12L** Long manual screwdriver
	**TIND** Parallelism indicator

	code	description
	**TDINA**	Dynamometric ratchet 20-55 N*cm

Materials
The items are made of 17 4PH (AISI 630) hardened stainless steel and they undergo electro-cleaning in acid bath and subsequent ultrasonic cleaning.

Operating direction
After inserting the driver in its seat, adjust the torque to apply by screwing or unscrewing the upper side of the wrench up to get the proper N*cm. Regulate to the scale end to use the wrench as a fixed ratchet.

For properly using the dynamometric wrench, when torque is applied to the driver, we recommend placing the finger in the position marked by the green arrow and not in the position marked by the red arrow.



	code	description
	**TMPRF**	Depth gauge

PROSTH

The TiSmart2 prostheses range includes a complete line for: Cemented prosthesis, Overdenture and Multiple screwed prosthesis, equipped with analog, transfer and healing screws of different lengths[33-37].

The constant internal hexagon size of the implant connection enables using the abutment for all the available diameters, thus providing laboratories and dental technicians with a much simpler choice of prosthesis components.

All the prostheses components include the screws to be used exclusively for final closing of the abutment in the patient, and not for the laboratory tests. The same screwdriver is used for all the prosthesis components, of any diameter available, including: healing screws, cap screws and transfer screws.

ESES

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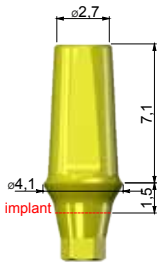
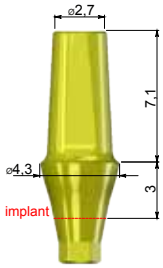
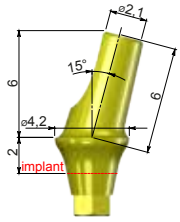
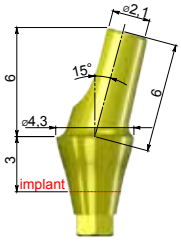
PREFORMED

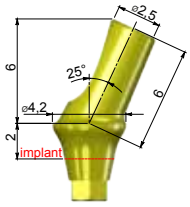
Preformed

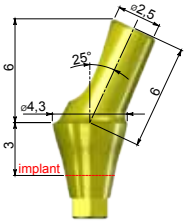
	code	description	H
	**TSKMD15**	Straight abutment (TSKVPR included)	1,5

	code	description	H
	**TSKMD30**	Straight abutment (TSKVPR included)	3

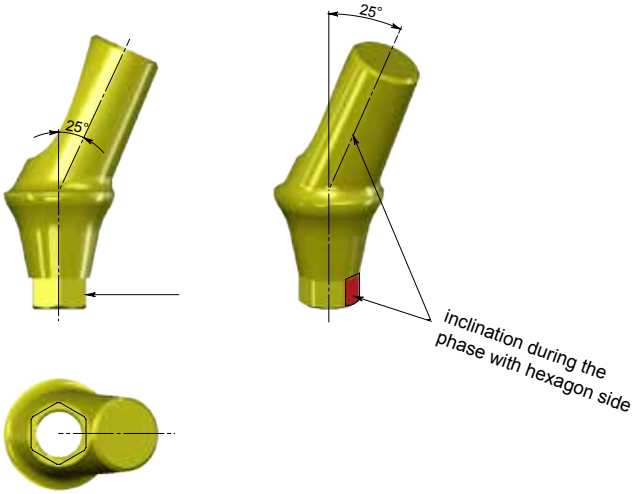
	code	description	H
	**TSKMA152**	15° angled abutment (TSKVPR included)	2

	code	description	H
	**TSKMA153**	15° angled abutment (TSKVPR included)	3

	code	description	H
	**TSKMA252**	25° angled abutment (TSKVPR included)	2

	code	description	H
	**TSKMA253**	25° angled abutment (TSKVPR included)	3

	code	description
	**TSKVPR**	Abutment screw



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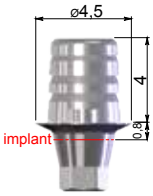
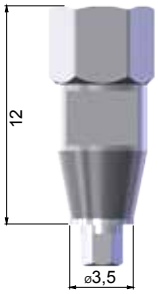
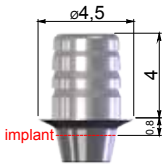
CAD-CAM ABUTMENTS

Cad-Cam abutments

	code	description	H
	**TSKCAM**	Cad-Cam abutment (TSKVPR included)	
	**TSKTI**	Ti-Base abutment (TSKVPR included)	0,8
	**TSKVPR**	Abutment screw	

	code	description	H
	**TSKINTRA**	Scan Body (TSKVPR included)	
	**TSKTIR**	Ti-Base abutment (TSKVPR included)	0,8
	**TSKANCAD**	Analog of Scan body	

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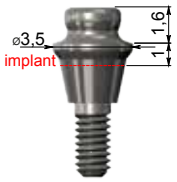
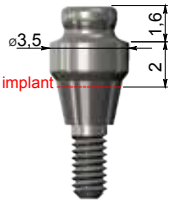
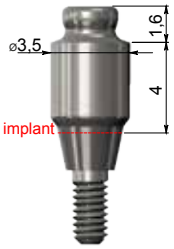
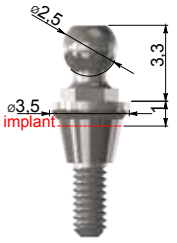
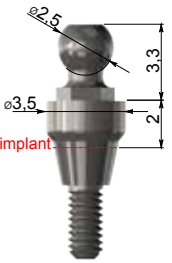
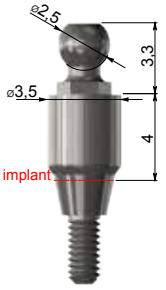
REMOVABLE PROSTHESIS

	code	description	H
	**TSKEQ1**	Equator abutment	1
	**TSKEQ2**	Equator abutment	2

	code	description	H
	**TSKEQ4**	Equator abutment	4
	**774CHE**	Equator abutment screwdriver	

	code	description	H
	**TSKMS1**	Ball abutment	1
	**TSKMS2**	Ball abutment	2

	code	description	H
	**TSKMS4**	Ball abutment	4
	**771CEF**	Ball abutment screwdriver	

	code	description	H
	**EQCAP01**	Equator cap abutment	1

	code	description	H
	**MSCAP01**	Ball abutment cap	2

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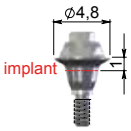
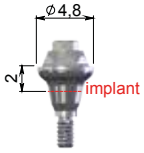
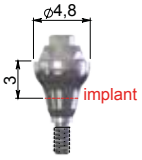
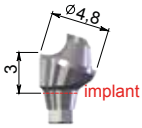
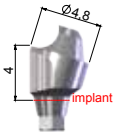
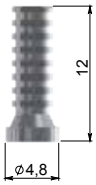
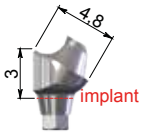
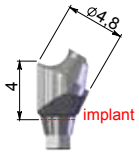
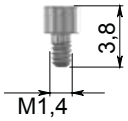
MFA ABUTMENTS

MFA abutments

code		code		code	
	**TSK001** straight MFA H=1		**TSK002** straight MFA H=2		**TSK003** straight MFA H=3
	**TSK173** 17° angled MFA (TSK100001 included)		**TSK174** 17° angled MFA (TSK100001 included)		**TIS100222** temporary abutment of MFA (TIS100003 included)
	**TSK303** 30° angled MFA (TSK100001 included)		**TSK304** 30° angled MFA (TSK100001 included)		**TIS900002** MFA castable abutment (TIS100003 included)
	**TIS100304** H=4 MFA healing screw		**TIS100306** H=6 MFA healing screw		**TIS100308** H=8 MFA healing screw
	**TIS100003** M 1.4 MFA prosthetic screw		**TSK100001** MFA prosthetic screw		**TPOMFA** Driver for angled MFA
	**TCRMFA** Screwdriver for stright MFA				

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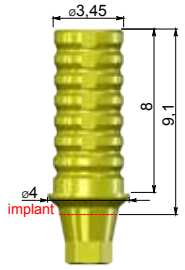
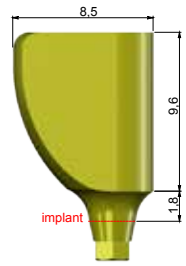
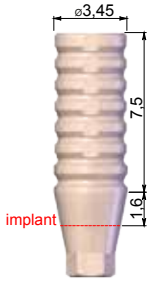
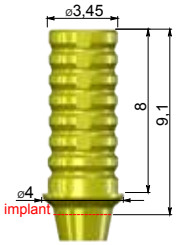
TEMPORARY AND MILLABLE ABUTMENTS

Temporary and millable abutments

	code	description	H
	**TSKMPN**	Temporary abutment with hexagon (TSKVPR included)	1,1
	**TSKMF**	Millable abutment (TSKVPR included)	1,8
	**TSKPEEK**	Peek abutment	1,6

	code	description	H
	**TSKMPR**	Temporary abutment without hexagon (TSKVPR included)	1,1
	**TSKCRCO**	Castable abutment with Cr-Co base (TSKVPR included)	0,8
	**TSKVPR**	Abutment screw	

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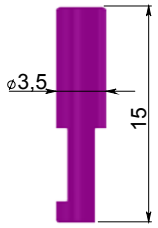
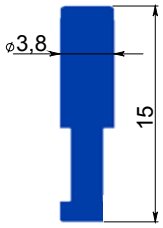
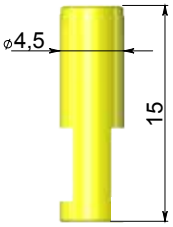
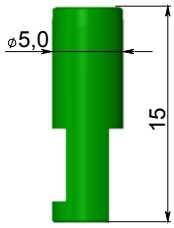
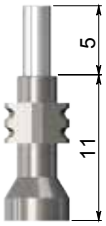
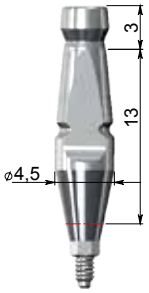
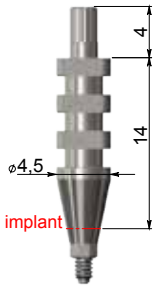
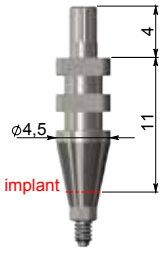
TRANSFERS AND ANALOGS

	code	description	Ø
	**TTIAN34**	Implant analog	3,5
	**TTIAN37**	Implant analog	3,8
	**TTIAN45**	Implant analog	4,5
	**TTIAN50**	Implant analog	5,0
	**TIS900001**	MFA analog	

	code	description
	**TIS900003**	Transfer MFA (screw included)
	**TSKTRST**	Closed tray transfer (screw included)
	**TSKTR**	Pick-up technique transfer (screw included)
	**TSKTRSH**	Pick-up technique short transfer (screw included)

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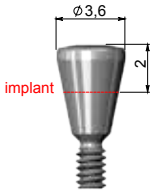
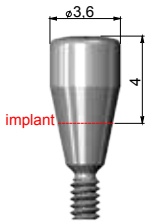
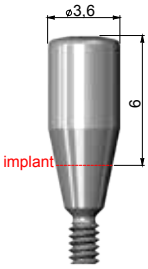
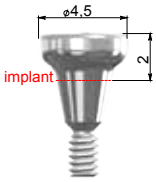
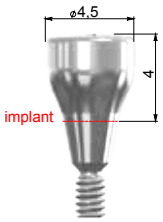
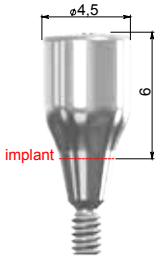
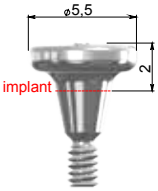
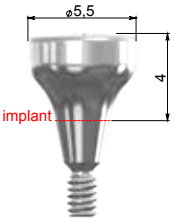
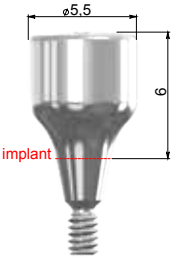
HEALING SCREWS

Healing screws

	code	description	H
	**TSKVG2**	Healing screw Ø 3,6	2
	**TSKVG4**	Healing screw Ø 3,6	4
	**TSKVG6**	Healing screw Ø 3,6	6

	code	description	H
	**TSKVG452**	Healing screw Ø 4,5	2
	**TSKVG454**	Healing screw Ø 4,5	4
	**TSKVG456**	Healing screw Ø 4,5	6
	**TSKVG552**	Healing screw Ø 5,5	2
	**TSKVG554**	Healing screw Ø 5,5	4
	**TSKVG556**	Healing screw Ø 5,5	6

PACKAGING

All TiSmart2 prosthesis components are kept inside a 3-compartment decontaminated blister made of PETG, sealed with Tyvec. The box keeps the items (abutment screws) decontaminated and allows one to use just one item without opening all the other compartments. The central compartment contains the instructional leaflet with the technical information and the instructions for use of the prothesis components. Packaging is carried out at the company in the clean room, if required.

Open the top of the blister by lifting the Tyvec cover from the end where the LABORATORY SCREW abutment is kept.

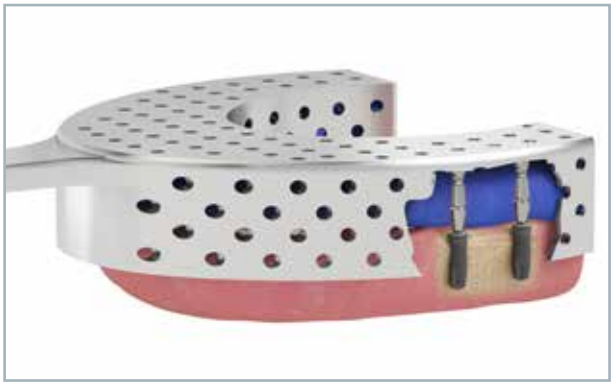
Open the cover until the compartment containing the instructions for use is open. Remove the abutment with the red screw that should be used only for laboratory tests and not for final closing. Leave compartment 4 closed.

The screw contained in department 3 (PATIENT SCREW) is decontaminated and should be opened at the moment of use for the final closing of the abutment in the patient.

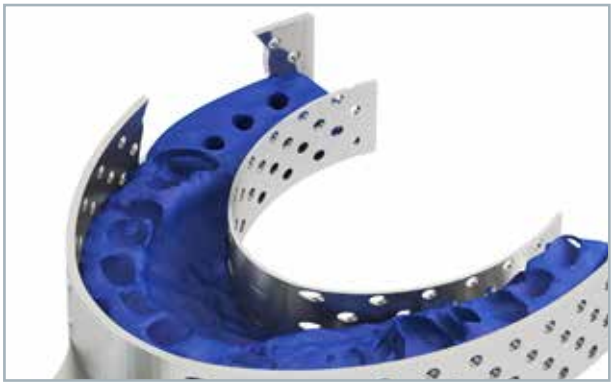
PROTHESIS

CLOSED TRAY PROTOCOL (with standard tray)

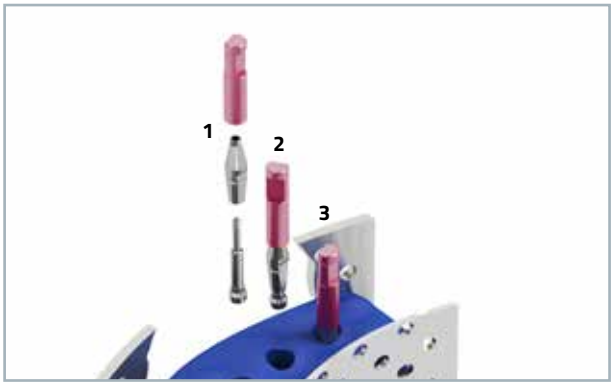
1 Remove the recovery screw, place the TSKTRST transfer connected to the implant and tighten the screw manually and also using the short TDR12C screwdriver. Check the screw is firmly tightened, preferably by taking an intra-oral X-ray.



2 Place the standard cast tray containing the appropriate cast material (which must be elastic so it can be removed from the transfers) and check that all the transfers are covered.



3 After the necessary time for the cast material to harden, slide out the tray.

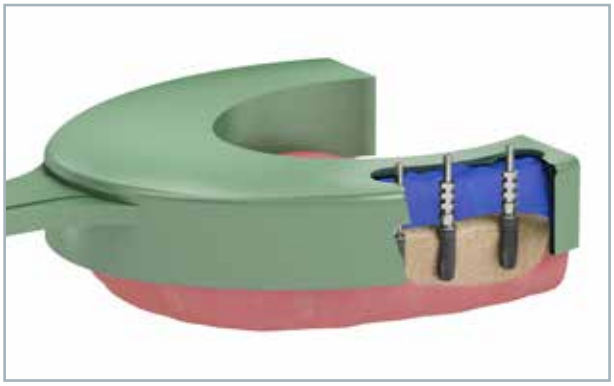


4 Unscrew the transfer screw from the implant, remove the transfer and connect it with its analog, and reposition the transfer+analog in the same seat where it was previously placed. Number the transfers if necessary. Consign to the laboratory for them to make the plaster cast.

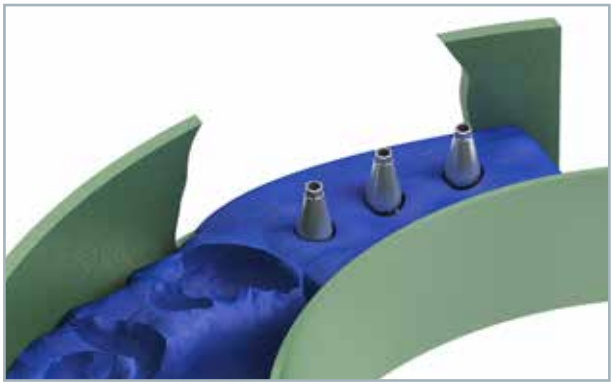
PROTOCOLS

OPEN TRAY PROTOCOL (with individual cast-tray)

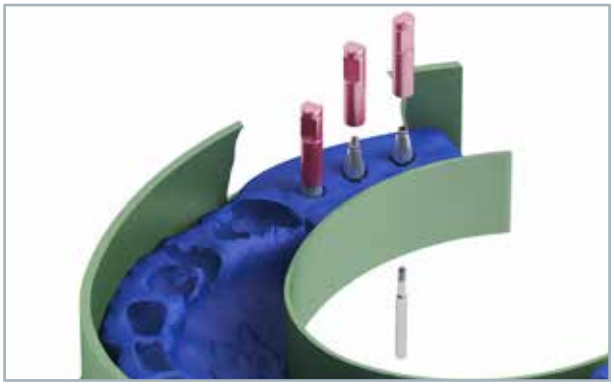
1 Remove the recovery screw, place the TSKTR transfer connected to the implant and tighten the screw manually and also using the short TDR12C screwdriver. Check the screw is firmly tightened, preferably by taking an intra-oral X-ray.



2 Prepare the individual cast tray, drilling in line with the closing screw. Place the cast tray containing the appropriate cast material (use a rigid material). For greater precision, it is advisable to fill the spaces along the transfer base with a precision material. Check the screws jut out of the cast tray.



3 After the necessary hardening time, unscrew the transfer screws (using the TDR12C screwdriver). When the cast tray is removed the transfers are also removed, which remain embedded in the cast material.



4 Screw the analogs to their transfers using the previously unscrewed screw. Consign to the laboratory for them to make the plaster cast. .

PROTHESIS

ALL ON 4 PROTOCOL WITH M.F.A.

1 Insert the implants, 4 if in the maxilla, 6 if in the mandible, following the All-on 4 protocol. The correct position, distance and inclination of the implants will ensure the best results in terms of prosthesis, function and long-life.

2 For easier positioning of the distal MFA use the TPOMFA driver. Ensure the angled MFA are correctly positioned, check the best parallelism between all 4 MFA using the TPOMFA driver. Tighten the screw using the TDR12C or TDR12L screwdriver, or the screwdriver with the ratchet attachment TCR12L at 25 N*cm. To screw down the straight MFA use the TCRMFA spanner (page 49) with ratchet attachment. Ensure they are correctly tightened at 25 N*cm. .

3 To take the cast, use the TIS900003 transfers, screwing them simultaneously onto all the MFA, and take the pick-up cast following the protocol on page 59.

4 Screw on the prosthesis using the 4 TIS100003, screws, supplied with the TIS900002 abutments, previously modelled by the laboratory and incorporated into the prosthesis. If the temporary TIS100222 abutments are used, prepare a prosthesis with through holes of the correct diameter, rebase in the mouth and file any projections.

PROTOCOLS

RECOVERY SCREWS

1 After identifying the implant seat, cut the flap, unscrew the cap screw that closes the implant. Choose the most appropriate recovery screw from the three available diameters of 3.6, 4.5, 5.5 according to the diameter of the crown to be used, and define the three available heights of 2, 4, 6 mm according to the thickness of the gums. The recovery screw must jut out from the tissue by at least 1 mm.

2 Screw down the recovery screw using the TCR12C screwdriver, without drilling. Stitch the flap around the recovery screw. Leave in place for at least 7 days until the tissues are completely healed and remodelled. Proceed with the cast taking techniques (pages 58-59).

EQUATOR ABUTMENTS

1 Abutments with Equator connections enable fixing movable prostheses unparalleled between the implants by up to 50°. The pink EQCAP01 cap, supplied with the Equator abutment, has a holding capacity of 25 N, and is housed in the specific container that is fixed onto the patient's prosthesis in line with the implant projection.

BALL ABUTMENTS

1 Abutments with ball attachments enable fixing movable prostheses unparalleled between the implants by up to 28°. The pink MSCAP01 cap, supplied with the abutment, has a holding capacity of 25 N, and is housed in the specific container that is fixed onto the patient's prosthesis in line with the implant projection. Check it is correctly closed at 25 N*cm.

ASSISTED

Leader Medica, in collaboration with Dentists, has developed their proprietary software WINMED®, which enables designing and producing surgical templates and laboratory models using a 3D printer, that are then used in computer assisted implant surgery. WINMED® is open software and does not need previously created libraries.

Acquiring the DICOM file from the TC and subsequent interpolation, enables simple and fast design of the surgical template according to the patient's clinical and prosthesis needs.

The file.stl can be sent directly to the 3D printer. The software also enables producing laboratory models, for precise production of the temporary prosthesis when needed for immediate surgical interventions. A simple surgical kit with a set of different height stops, enables performing assisted surgery easily and fast. For completion, the laboratory also has a range of accessories available for the precise and fast production of the temporary prosthesis.

SURGERY

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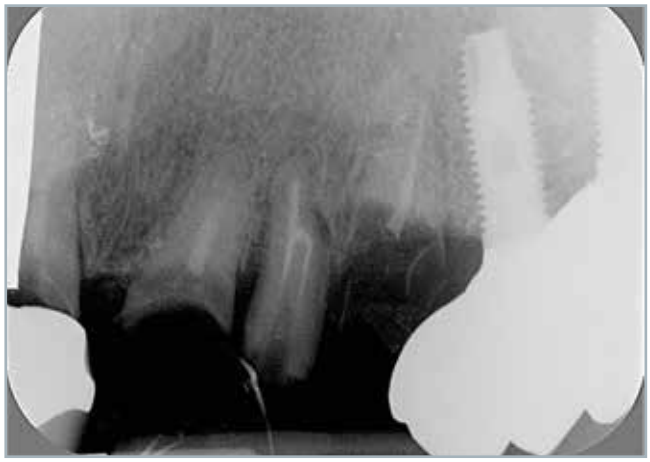
	code	description
	**AMUCOTOMO**	Tissue punch's contra-angle connection
	**PIN173**	17° MFA indicator - H3
	**PIN303**	30° MFA indicator - H3
	**BOCCOLA**	Boccola per provvisorio

	code	description
	**MUCOTOMO**	Tissue punch
	**PIN174**	17° MFA indicator - H4
	**PIN304**	30° MFA indicator - H4

	code	description
	**TBUSSG**	Titanium bush
	**TBUSSPKG**	Peek bush
	**TDR12LG**	temporary abutment screwdriver
	**TSKAN48G**	Model's analog
	**TSTOPC20(xx)G**	M4 stop
	**TSTOPC42(xx)G**	Stop M5

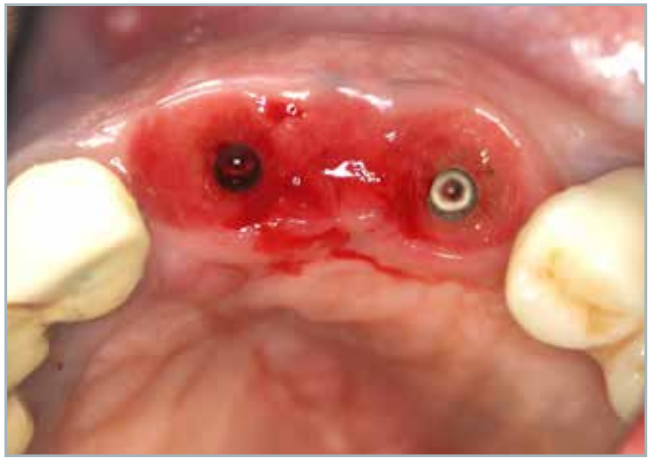
IMMEDIATE POST EXTRACTIVE IMPLANTS E IMMEDIATE LOADING TO ANTERIOR MAXILLA

Prof. Giovanni Battista Menchini Fabris DDS, PhD, MSc University G. Marconi Roma (Italy)



Extractions #21 #23 residual roots

Immediate provisional prosthesis for tissues conditioning



Soft tissues modeling

5 months later: impression for final prosthesis

Customized impression transfers for soft tissues registration

Final prosthesis; screwed zirconia crowns

IMMEDIATE POST EXTRACTIVE IMPLANTS E IMMEDIATE LOADING TO ANTERIOR MANDIBLE

Prof. Giovanni Battista Menchini Fabris DDS, PhD, MSc University G. Marconi Roma (Italy)

Heavy smoker diabetes 2

Partial removable prosthesis to posterior

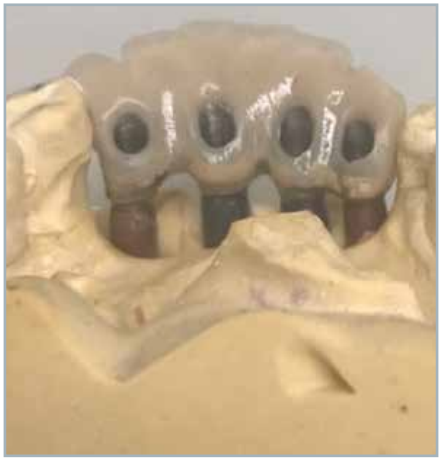
Minimally invasive extractions

Autologus bone addiction in fresh socket

Flapless implants placement

Provisional abutment

Parallelism check with transfers long screws



Provisional reinforced Immediate loading prosthesis

Soft tissue adaptations to provisional immmediate prosthesis

1) Sanz M, Cecchinato D, Ferrus J, Pjetursson EB, Lang NP, Jan L. A prospective, randomized-controlled clinical trial to evaluate bone preservation using implants with different geometry placed into extraction sockets in the maxilla. Clin. Oral Impl. Res. 21, 2009:13–21.

2) Albrektsson T, Zarb G, Worthington P, Eriksson AR. The long-term efficacy of currently used dental implants: A review and proposed criteria of success. Int. J. Oral Maxillofac. I2A

3) Kim JJ, Lee DW, Kim CK, Park KH, Moon IS. Effect of conical configuration of fixture on the maintenance of marginal bone level: Preliminary results at 1 year of function.
Clin. Oral Implants Res. 2010;21(4):439-44.

4) Nordin T, Jonsson G, Nelvig P, Rasmusson L. The use of a conical fixture design for fixed partial prostheses. A preliminary report. Clin. Oral Implants Res. 1998;9(5):343-7.

5) F.M. He, G.L. Yang, Y.N. Li, X. X. Wang, S.F. Zhao. Early bone response to sandblasted, dual acid-etched and H2O2/HCl treated titanium implants: an experimental study in the rabbit.
Int. J. Oral Maxillofac. Surg. 2009; 38:677-681.

6) Albrektsson T, Zarb GA. Current interpretations of the osseointegrated response: Clinical significance. Int. J. Prosthodont 1993;6(2):95-105.

7) Morra M., Cassinelli C., Crespi R., Covani U. Valutazione in vitro di una nuova superficie implantare con morfologia nano strutturata.
Il Circolo, Rivista Periodica di Odontostomatologia, 2004;1:27-34.

8) Wennerberg A., Albrektsson T. Effects of titanium surface topography on bone integration: a systematic review. Clin. Oral Implants Res., 2009; 20(4):172-184.

9) Pappalardo S., Milazzo I., Nicoletti G., Baglio O. O., Blandino G., Scalini L., Mastrangelo F., Tete S. Dental implants with locking taper connection versus screwed connection: microbiologic and scanning electron microscope study.
International Journal of Immunopathologic Pharmacology, 20 (Suppl1) Jan-Mar:13-17, 2007

10) Albrektsson T., Johansson C. Osteoinduction, osteoconduction and osseointegration.
European Spine Journal, 2001; 10:S96-S10111.

11) Strietzel F.P., Neumann K., Hertel M. Rewiew article: impact of platform switching on arginal peri-implant bone-level changes. A systematic review and meta-analisis.
Clin. Oral Implants Res., 2014;00:1-16

12) Cecchinato D, Parpaiola A, Lindhe J. Mucosal inflammation and incidence of crestal bone loss am11) Donati M, La Scala V, Di Raimondo R, et al. Marginal bone preservation in single-tooth replacement: A 5-year prospective clinical multicenter study.
Clin. Implant Dent Relat Res. 2013;E-pub July 25, doi:10.1111/cid.12117.

13) Donati M, La Scala V, Di Raimondo R, et all. Marginal bone preservation in single-tooth replacement: A 5-year prospective clinical multicenter study.
Clin. Implant Dent Relat. Res. 2013;E-pub July 25, doi:10.1111/cid.12117.

14) Liaje A, Ozkan YK, Ozkan Y, Vanlioglu B. Stability and marginal bone loss with three types of early loaded implants during the first year after loading. Int. J. Oral Maxillofac. Implants 2012;27(1):162-72.

15) Renvert S, Lindahl C, Persson RG. The incidence of periimplantitis for two different implant systems over a period of thirteen years. J. Clin. Periodontol. 2012;39(12):1191-7.

16) Vervaeke S, Dierens M, Besseler J, De Bruyn H. The influence of initial soft tissue thickness on peri-implant bone remodeling. Clin. Implant Dent Relat. Res 2014;16(2):238-47.

17) Vervaeke S, Collaert B, De Bruyn H. The effect of implant surface modifications on survival and bone loss of immediately loaded implants in the edentulous mandible.
Int. J. Oral Maxillofac. Implants 2013;28(5):1352-7.

18) Canullo L, Baffone GM, Botticelli D, Pantani F, Beolchini M, Lang NP. EFFECT OF WIDER IMPLANT/ABUTMENT MISMATCHING: AN HISTOLOGICAL STUDY IN DOGS Clin. Oral Implants Res., 22(9), 2011:910

19) Serrano-Sánchez P, Calvo-Guirado JL, Manzanera-Pastor E, Lorrio- Castro C, Bretones- López P, Pérez-Llanes JA. THE INFLUENCE OF PLATFORM SWITCHING IN DENTAL IMPLANTS. A LITERATURE REVIEW
Medicina Oral Patología Oral Cirugía Bucal. 2011 May 1;16 (3):e400-5

20) Kutan-Misirlioglu E, Bolukbasi N, Yildirim-Ondur E, Ozdemir T. Clinical and radiographic evaluation of marginal bone changes around platform-switching implants placed in crestal or subcrestal positions: A randomized controlled clinical trial. Clin. Implant Dent Relat. Res. 2014;E-pub July 22, doi:10.1111/cid.12248.

21) Noelken R, Donati M, Fiorellini J, et al. Soft and hard tissue alterations around implants placed in an alveolar ridge with a sloped configuration. Clin. Oral Implants Res. 2014;25(1):3-9.

22) Misch CE, Judy KW. Classification of partially edentulous arches for implant dentistry.
Int. J. Oral Implantol. 1987;4(2):7-13.

23) Cawood JI, Howell RA. A classification of the edentulous jaws.
Int. J. Oral Maxillofac. Surg. 1988; 17(4):232–36.

24) Roos J, Sennerby L, Lekholm U, et al. A qualitative and quantitative method for evaluating implant success: A 5-year retrospective analysis of the Branemark implant.
Int. J. Oral Maxillofac. Implants 1997;12(4):504-14.

25) Gökcen-Röhlig B, Meric U, Keskin H. Clinical and radiographic outcomes of implants immediately placed in fresh extraction sockets. Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod. 2010;109(4):1-7.

26) Thor A, Ekstrand K, Baer RA, Toljanic JA. Three-year follow-up of immediately loaded implants in the edentulous atrophic maxilla: A study in patients with poor bone quantity and quality.
Int. J. Oral Maxillofac. Implants 2014;29(3):642-9.

27) Cooper LF, Moriarty JD, Guckes AD, et al. Five-year prospective evaluation of mandibular overdentures retained by two microthreaded, tioblast nonsplinted implants and retentive ball anchors.
Int. J. Oral Maxillofac. Implants 2008;23(4):696-704.

28) Lee DW, Choi YS, Park KH, Kim CS, Moon IS. Effect of microthread on the maintenance of marginal bone level: A 3-year prospective study. Clin. Oral Implants Res. 2007;18(4):465-70.

29) Lee DW, Park KH, Moon IS. The effects of off-axial loading on periimplant marginal bone loss in a single implant. J. Prosthet. Dent. 2014;112(3):501-7.

30) Van de Velde T, Collaert B, Sennerby L, De Bruyn H. Effect of implant design on preservation of marginal bone in the mandible. Clin. Implant Dent. Relat. Res. 2010;12(2):134-41.

31) Laurell L, Lundgren D. Marginal bone level changes at dental implants after 5 years in function: A meta-analysis. Clin. Implant Dent. Relat Res. 2011;13(1):19-28.

32) Ghoveizi R, Alikhasi M, Siadat M-R, Siadat H, Sorouri M. A radiographic comparison of progressive and conventional loading on crestal bone loss and dentistry in single dental implants: A randomized controlled trial study. J Dentistry, Teheran Univ. Med. Sci. 2013;10(2):155-63.

33) Mertens C, Steveling HG, Stucke K, Pretzl B, MeyerBaumer A. Fixed implant-retained rehabilitation of the edentulous maxilla: 11-year results of a prospective study. Clin. Implant Dent. Relat Res. 2012;14(6):816-27.

34) Mertens C, Steveling HG. Implant-supported fixed prostheses in the edentulous maxilla: 8-year prospective results. Clin. Oral Implants Res. 2010;22(5):464-72.

35) Mumcu E, Bilhan H, Geckili O. The influence of healing type on marginal bone levels of implants supporting mandibular overdentures: A randomized clinical study. Indian J. Dent Res. 2012;23(4):514-8.

36) Slot W, Raghoebar GM, Vissink A, Meijer HJ. Maxillary overdentures supported by four or six implants in the anterior region; 1-year results from a randomized controlled trial.
J. Clin. Periodontol. 2013;40(3):303-10.

37) Toljanic JA, Baer RA, Ekstrand K, Thor A. Implant rehabilitation of the atrophic edentulous maxilla including immediate fixed provisional restoration without the use of bone grafting: A review of 1-year outcome data from a long term prospective clinical trial. Int. J. Oral Maxillofac. Implants 2009;24(3):518-26.

38) Cooper LF, Raes F, Reside GJ, et al. Comparison of radiographic and clinical outcomes following immediate provisionalization of single-tooth dental implants placed in healed alveolar ridges and extraction sockets. Int. J. Oral Maxillofac. Implants 2010;25(6):1222-32.

39) Cooper LF, Reside GJ, Raes F, et al. Immediate provisionalization of dental implants placed in healed alveolar ridges and extraction sockets: A 5-year prospective evaluation.
Int. J. Oral Maxillofac. Implants 2014;29(3):709-17.

40) Donati M, La Scala V, Billi M, et all. Immediate functional loading of implants in single tooth replacement: A prospective clinical multicenter study. Clin. Oral Implants Res. 2008;19(8):740-48.

41) Gulje F, Raghoebar GM, Ter Meulen JW, Vissink A, Meijer HJ. Mandibular overdentures supported by 6-mm dental implants: A 1-year prospective cohort study.
Clin. Implant Dent. Relat. Res. 2011;14(Supplement 1):e59-e66.

42) Koutouzis T, Koutouzis G, Tomasi C, Lundgren T. Immediate loading of implants placed with the osteotome technique: One-year prospective case series. J. Periodontol. 2011;82(11):1556-62.

43) Raes F, Cosyn J, De Bruyn H. Clinical, aesthetic, and patient-related outcome of immediately loaded single implants in the anterior maxilla: A prospective study in extraction sockets, healed ridges, and grafted sites. Clin. Implant Dent. Relat. Res. 2013;15(6):819-35.

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