

TiSmart2[®]
by Shild Biomedik GmbH

CARE ABOUT YOU...



THE COMPANY

The company was founded in 1995 and is based in Padua, Italy. In collaboration with academics and international 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.

Production is carried out at the company, from the raw materials to the manufacturing and packaging that takes place in the cleanroom.



PRODUCTION

The entire production process of the TiSmart2 implant is managed by the engineering dept of the company. 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. The UNI EN 13485:2016 certification of the entire production process obtained from independent certifying agencies, confirms the qualitative superiority of products.

- 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



QUALITY CONTROL

Tismart2 is a certified company UNI EN 13485-2016

The whole productive process, which is conducted within the company, allows us to verify and certify that each product (implant and prostheses) reaches high standards.

The first verification phase, which is conducted on every 10 pieces, utilises optical microscope and automated laser devices. This allows to verify, in real time, the correspondence with the required mechanical tolerances during the projecting phase. Sequentially, each piece produced moves to the quality department to verify the dimensional correspondence with laser on every produced piece.

A real **ONE** to **ONE** control.

Several washing cycles with solvent and ultrasound are made in order to eliminate all traces of organic contamination. After this, the implants are ready for the acid etched process, conducted with two different acid baths. This industrial process is necessary to increase the irregularity on the surface to make it osteo inductive and osteoconductive, and to activate the biological osseointegration processes once attached to the bone. Furthermore, this process does not utilise the common process which involves sandblasting with aluminium components.


Finally, the implant is decontaminated. This occurs through a micro atomic cleaning process. The surface of the implant is heavily hit by atoms ionized of gases (argon and nitrogen) necessary to remove 100% of every organic trace. Sequentially the implant is inserted into a blister and sterilised with beta rays, to eliminate every bacterial contamination.

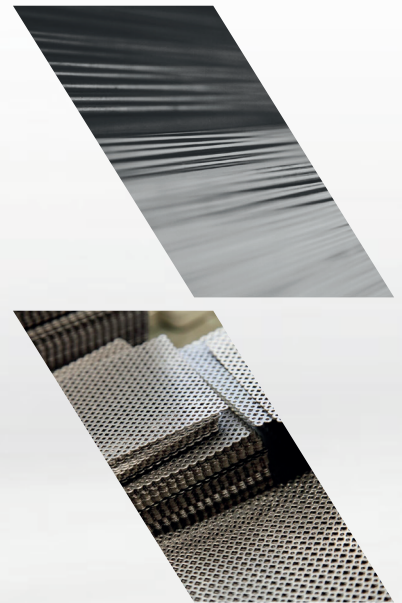


RAW MATERIALS

TiSmart2 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 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.



ALUMINIUM FREE



On the market there are different types of Titanium divided into degrees of material purity. Grades 1,2,3 and 4 are called "99.9% commercially pure titanium", from grade 5 to 23 we have Titanium alloys, which therefore contain other chemical elements among which; Aluminium, Iron, Vanadium.

It is widely documented in international literature how Aluminium is a non-biocompatible, neurotoxic element that appears to be involved in some serious diseases such as Alzheimer's. While many companies employ Titanium alloys of grade 5 or 23 for the production of dental implants, TiSmart2 uses, as a precaution, pure Titanium grade 4, therefore free from contaminants, such as Aluminium. TiSmart2 also does not adopt any industrial process, for example in the process of surface roughening, with components based on Aluminium.

For these reasons TiSmart2, on the international license, which will be delivered to you after the intervention, certifies the plant as Aluminium Free Processing.

TISMART2

The Bone Level TiSmart2 System is made from 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 stability¹⁻⁴.

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 seal. 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 tissue¹⁰⁻¹⁷, to the benefit of the long term aesthetic result¹⁸⁻²¹.

The variable geometry spirals enable modulating the implant primary stability during insertion, in all bone hardness conditions²²⁻²⁶. The micro-threading on the coronal area reduces bone reabsorption²⁷⁻³² and therefore improves the long-term performance.

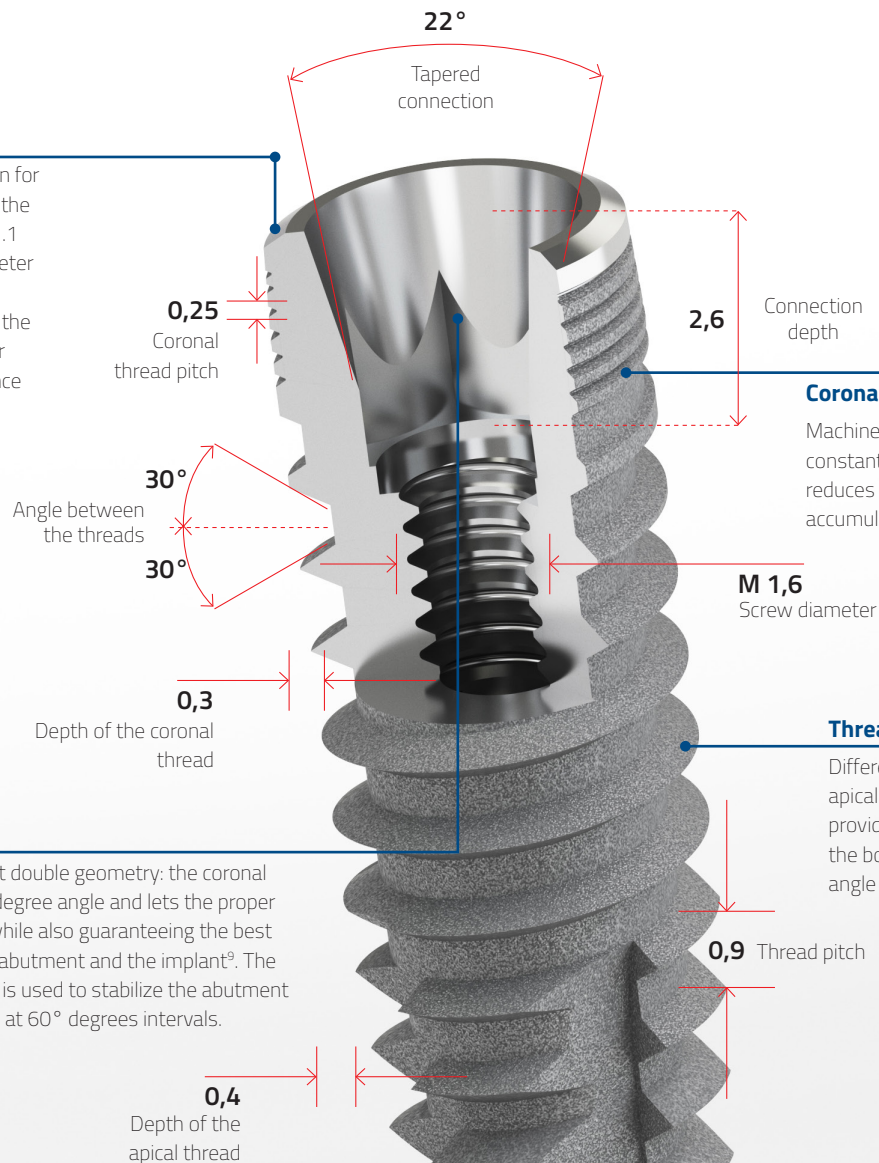
The apical incisions mean the implant is self-taping and easy to insert and also guarantees excellent anti-rotation effect.



INNOVATIVE DESIGN

Platform switching

The constant size of the connection for all diameters makes it possible for the prosthesis 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 tissues¹⁰⁻²⁷ for improving the aesthetic performance over the long period¹⁸⁻²¹.



Coronal morphology

Machined in the first 0.5 mm and constant pitch microthread, which reduces bone resorption²⁷⁻³² 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

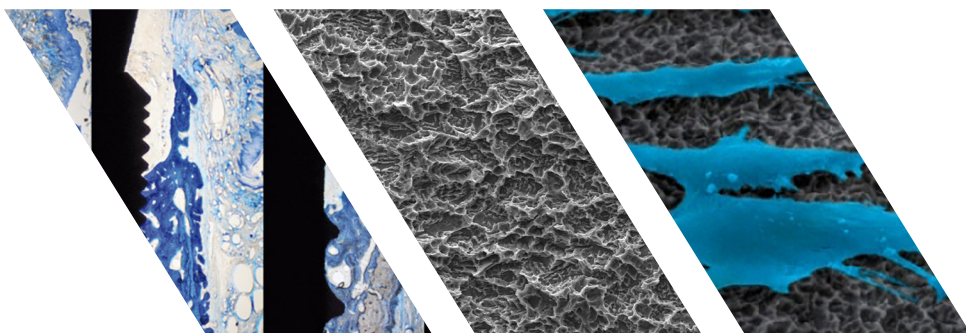
Rounded to protect the critical anatomic structures such as the mandibular nerve or the Schneiderian membrane.

SURFACE





The TiSmart2 implant line is made with a double acid-etched process that eliminates “sandblasting” to keep away from the possible source of aluminum contamination as the general usage of the %95 implant system worldwide.

This treatment is extensively documented in international literature and allows for a superficial roughness of $Ra=1.3\text{ }\mu\text{m}$, 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.



SIZE&CODING

	 code	 code	 code	 code
7,0 L [mm]	-	-	-	TTI5007
8,5 L [mm]	TTI3485	TTI3785	TTI4585	TTI5085
10 L [mm]	TTI3410	TTI3710	TTI4510	TTI5010
11,5 L [mm]	TTI3411	TTI3711	TTI4511	TTI5011
13 L [mm]	TTI3413	TTI3713	TTI4513	TTI5013
15 L [mm]	TTI3415	TTI3715	TTI4515	TTI5015

SURGICAL KIT

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.



DRILLS

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. They ensure higher cut precision and longer duration compared to other drills in the market.

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.

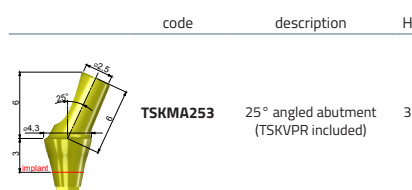
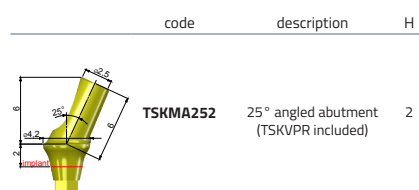
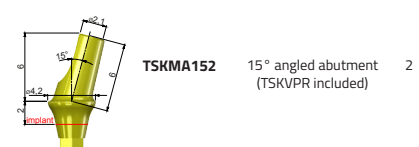
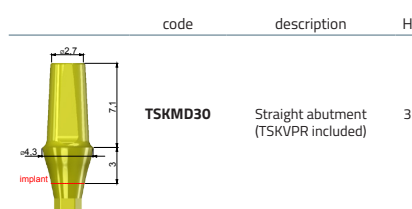
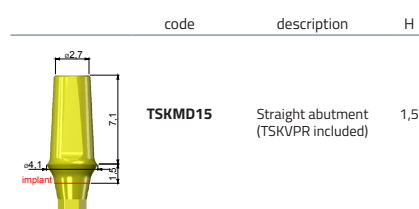


PREFORMED PROSTHESES

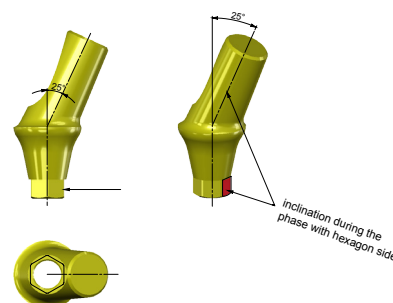
The TiSmart2 prostheses range includes a complete line for: Cemented prostheses, Overdenture and Multiple screwed prostheses, equipped with analog, transfer and healing screws of different lengths³³⁻³⁷.

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 prostheses components.

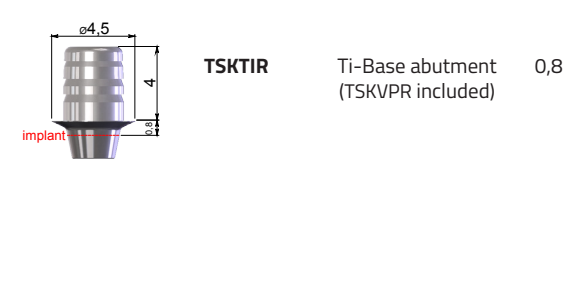
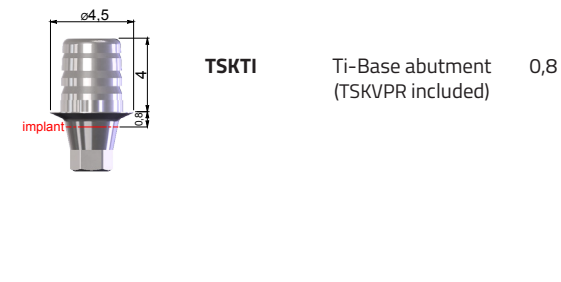
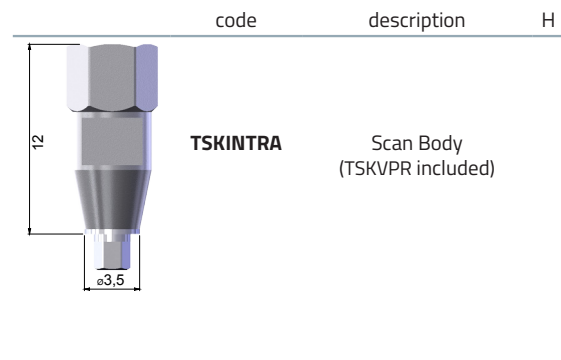
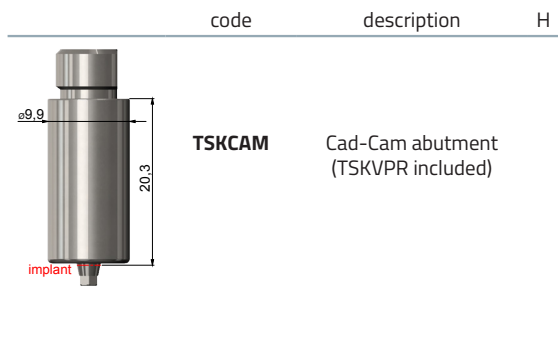
All the prostheses components include the screws to be used exclusively for final closing of the abutment in the patient and not for the laboratory tests. The same screwdriver is used for all the prosthesis components, of any diameter available, including: healing screws, cap screws and transfer screws.



TSKVPR
Abutment screw



CAD-CAM ABUTMENTS



TSKVPR Abutment screw



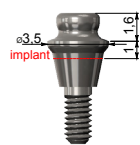
TSKANCAD Analog of Scan body

3shape 
exocad

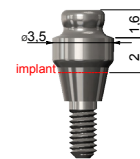


REMOVABLE PROSTHESIS

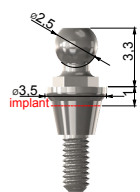
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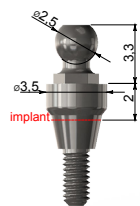
TSKEQ1	Equator abutment	1
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TSKEQ2	Equator abutment	2
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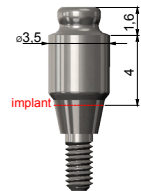


TSKMS1	Ball abutment	1
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TSKMS2	Ball abutment	2
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code	description	H
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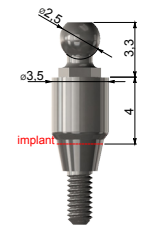


TSKEQ4	Equator abutment	4
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774CHE	Equator abutment screwdriver	
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code	description	H
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TSKMS4	Ball abutment	4
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771CEF	Ball abutment screwdriver	
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code	description	H
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EQCAP01	Equator cap abutment	1
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code	description	H
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MSCAP01	Ball abutment cap	2
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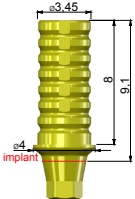
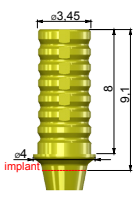
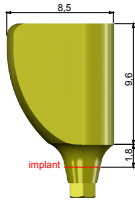
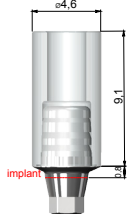
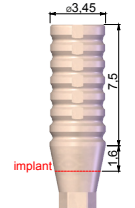



MFA ABUTMENTS

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



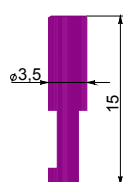
TEMPORARY AND MILLABLE ABUTMENTS

	code	description	H		code	description	H
	TSKMPN	Temporary abutment with hexagon (TSKVPR included)	1,1		TSKMPR	Temporary abutment without hexagon (TSKVPR included)	1,1
	TSKMF	Millable abutment (TSKVPR included)	1,8		TSKCRCO	Castable abutment with Cr-Co base (TSKVPR included)	0,8
	TSKPEEK	Peek abutment	1,6		TSKVPR	Abutment screw	



TRANSFERS & ANALOGS

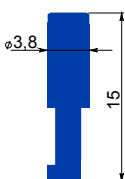
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TTIAN34

Implant analog

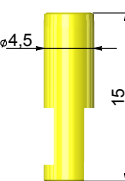
3,5



TTIAN37

Implant analog

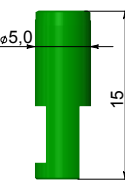
3,8



TTIAN45

Implant analog

4,5



TTIAN50

Implant analog

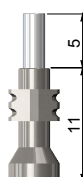
5,0



TIS900001

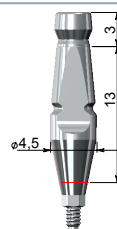
MFA analog

code	description
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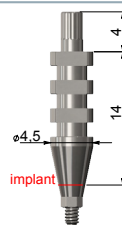
TIS900003

Transfer MFA
(screw included)



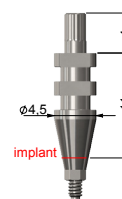
TSKTRST

Closed tray transfer
(screw included)



TSKTR

Pick-up technique transfer
(screw included)



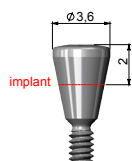
TSKTRSH

Pick-up technique
short transfer
(screw included)



HEALING SCREWS

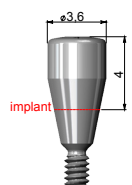
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TSKVG2

Healing screw
Ø 3,6

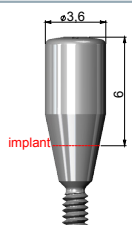
2



TSKVG4

Healing screw
Ø 3,6

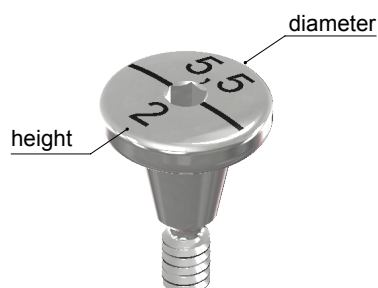
4



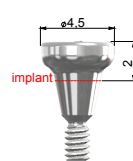
TSKVG6

Healing screw
Ø 3,6

6



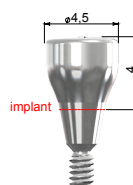
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TSKVG452

Healing screw
Ø 4,5

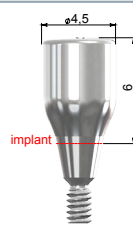
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TSKVG454

Healing screw
Ø 4,5

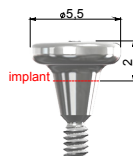
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TSKVG456

Healing screw
Ø 4,5

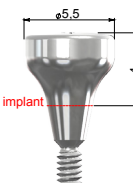
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TSKVG552

Healing screw
Ø 5,5

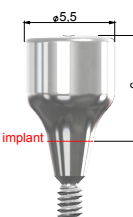
2



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 prosthesis components. Packaging is carried out at the company in the clean room, if required.



ASSISTED SURGERY

TiSmart2 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 CT and subsequent interpolation, enables simple and fast design of the surgical template according to the patient's clinical and prosthesis needs. The STL file can be sent directly to the 3D printer. The software also enable 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.



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- 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. Surg.* 1998;27(1):1–17.
- 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.
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- 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
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