

VENUS §



for everyone



SZUTEST

EC CERTIFICATE

AT SERTIFIKA

According to Annex II of the Directive 93/42/EEC on Medical Devices

93/42/AT Tıbbi Cihaz Yönetmeliği Ek II'ye göre

Full Quality Assurance System

Tam Kalite Güvencesi

Certificate Number: 2195-MED-2114402

Sertifika Numarası

Manufacturer: Üretici MEDISOLARİS SAĞLIK HİZMETLERİ SAN. ve TİC. LTD. ŞTİ.

Fatih Mah. 1191 Sk. B Blok Sit. B Blok Apt. No:28/1 Gaziemir, İzmir, TÜRKİYE

Product(s): Ürün(ler)

1. Dental Implants and Superstructures

Dental Implantlar ve Üstyapı Sistemleri
 Dental Implant Surgical Instruments

2. Dental Implant Cerrahi El Aletleri

Model(s):

MERKÜRHEX, VENÜSCON

Model(ler)

Reference Report No: MM0878-P001-R01, MM0878-P001-R02, MM0878-P001-R03

Referans Rapor No

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK II(madde 4 hariç) madde 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK II, Madde 5'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir.

Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır. Steril kondisyondaki sınıf I ürünler için kalite yönetim sistemi değerlendirmesi üretimin steril kondisyonun sağlanması ve korunmasıyla limilildir. Ölçüm fonksiyonlu sınıf I ürünler için Kalite yönetim sistemi değerlendirmesi üretimin cihazların metrolojik şartlara uyumunu sağlamasıyla limilildir.

This EC certificate is valid till 2024-05-26. Bu AT Sertifikası 2024-05-26 tarihine kadar geçerlidir.

Issue Date/Yayın Tarihi:

2021-05-24

Rukiye BALKAN Deputy General Manager Genel Müdür Yardımcısı

FR.MED.33 R:05

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL/TÜRKİYE

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MEDISOLARIS ABOUT US

Medisolaris has established in Izmir in 2020 by our team and has many years of experience in the sector in different fields. Medisolaris has started its operations as a domestic implant brand in order to meet the market needs in the best way.

Our company, set out to produce practical and innovative solutions, adopts a principle that aims to prioritize quality by analyzing the needs of the sector in the best way possible and presenting the right product in the right place.

Our team combines its high technical knowledge with expert sales capabilities, and is happy to understand user requests in the best way and to provide high quality service with competitive and innovative ideas.

Vision

swile for everyone

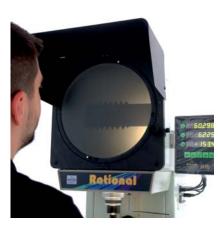
As Medisolaris, our vision is to contribute to the smiles of all patients in Turkey and around the world with our domestic implants that we designed using all the possibilities of technology.

Mission

As Medisolaris, our mission is to provide practical solutions to our physicians by developing a flexible production approach within the limits of quality, and contributing to domestic production with our superior technological infrastructure opportunities.

Selçuk KARA

Co-Founder





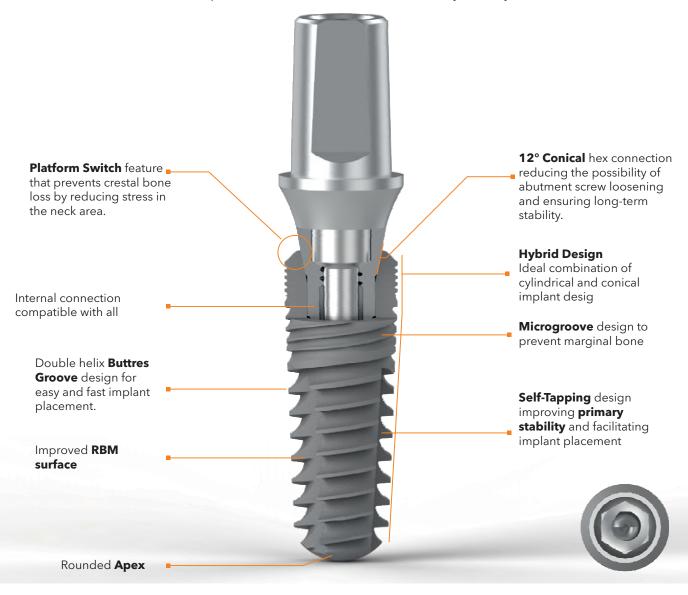






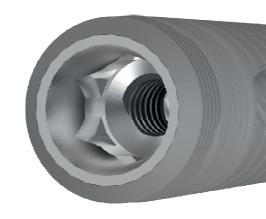
VENUSCON TECHNICAL SPECIFICATIONS

VenusCon Bone Level Implants offer excellent aesthetics and naturality for many indications.



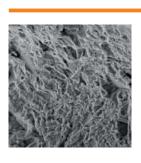
Conical Connection

Thanks to VenusCon Bone Level implants 12° Conical hex connection, the forces on the implant - Abutment - Connection Screw are distributed and not concentrated in a single point. Bacterial impermeability is ensured with the Conical Connection. Thanks to the minimum micro-movement, the least bone resorption in the marginal region and the least torque loss and loosening of the connecting screw are experienced. Excellent stability

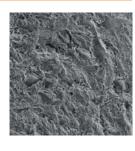












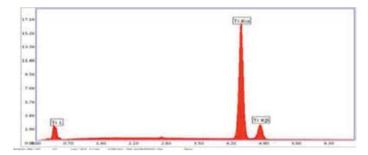
ENHANCED RBM SURFACE

All VenusCon Implants were surface roughened with the **RBM (Resordable Blast Media)** process. To achieve the desired roughness, the implant is sandblasted with hardened **Hydroxyapatite (beta-Tricalcium Phosphate, Alpha Tcp, Ttcp and Calcium Phosphate (CPP)** particles and then dissolved from the surface by a defined passivation process. Continuous surface smoothness is achieved to RA 1.5-2.3.

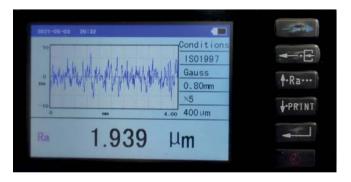
This surface treatment is designed to roughen the implant surface without leaving any residual embedded sand particles or residue on the implant.

This process involves sandblasting the implant surface with **Calcium Phosphate** material to create a macro topography and then performing the passivation process to remove the embedded **Hydroxyapatite Particles** from the environment.

Consequently, it results in a greater surface area for **Osseointegration**, improved attachment properties, increased biological fixation, and a rougher implant surface than conventional acid etching, which maximizes Implant-Bone contact.



As a result of the Edax Analysis performed at **Celal Bayar University**, no elements that cause biocontamination and negatively affect osseointegration were found.



Thanks to the improved new **RBM Surface**, excellent values compatible with bone morphology have been achieved, ensuring faster and better osseointegration quality.



All VenusCon Implants are manufactured from alloyed **TitaniumT16AI4V ELI (Grade 23).** This alloy has proven to be the ideal material for implant manufacture mainly due to its ability to integrate almost completely with bone. It is also biodegradable and offers **Chemical Stability** as well as superior mechanical qualities such as strength and durability. It is **40%** more durable than **Grade 4** in terms of mechanical forces.

The surface of **VenusCon Implants** is covered with a thin layer of **Titanium Oxide (TiO2).** In addition, surface roughening was achieved with the **RBM (Resordable Blast Media)** process. Calcium Phosphate is used for this improved surface technology. Calcium Phosphate is a biocompatible material. Thanks to this process, more bone-implant contact area was obtained by increasing the implant surface area.



VENUSCON TECHNICAL SPECIFICATIONS

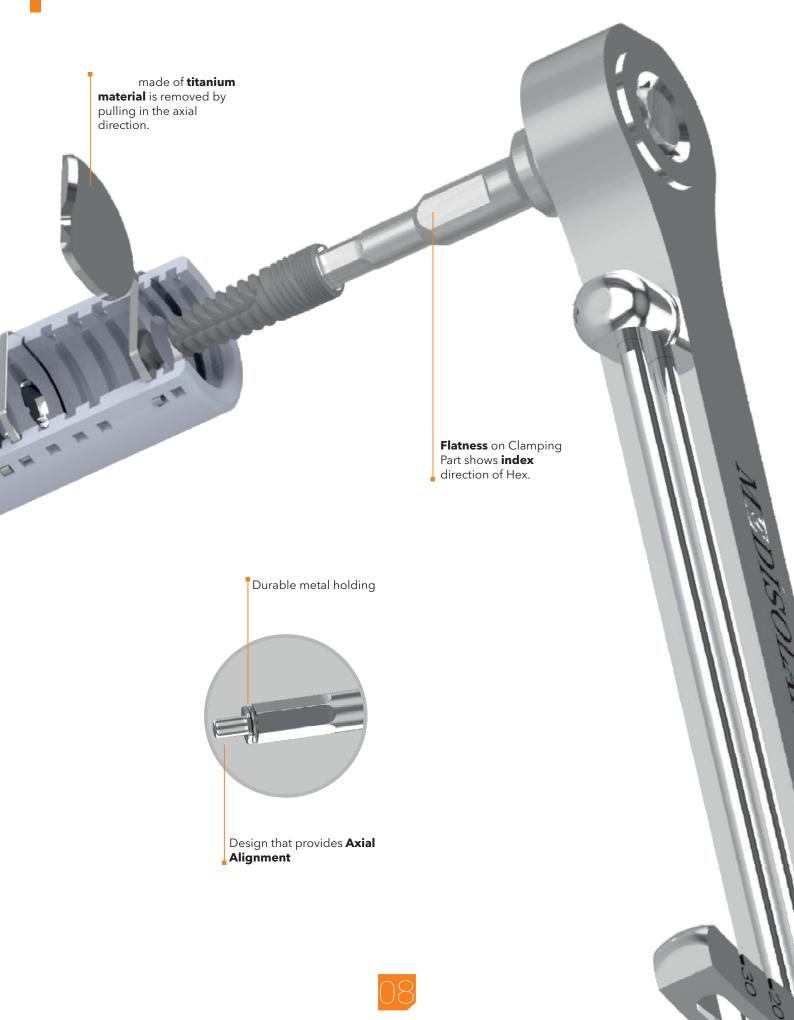
VenusCon Implants are presented in sterile blister and tube with implant cower screw.

Make sure that the safety strip of the tube cover of the **VenusCon Implant** in the sterile tube has not been opened before. **The Cover** on the hanger removed from the tube is removed by pulling in the axial direction. **Transfer and Tightening Part** is placed in such a way that the index direction and the implant index direction are parallel, and the implant is applied to the opened slot. Transfer and Tightening Part is removed by applying **5Ncm** force.

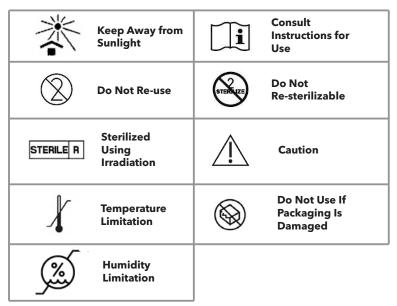


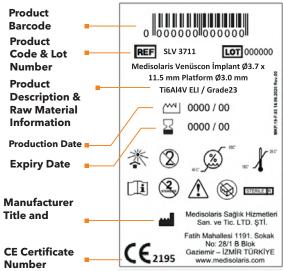


VENUSCON TECHNICAL SPECIFICATIONS



VENUSCONPACKAGING & LABEL

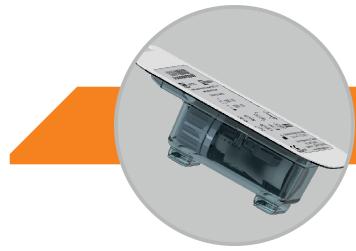




All **traceability** is ensured by the UTAKSIS ERP program specially prepared for the medical sector, through to the **Code and Lot Number** on the product labels.



Sterilization was carried out with Gamma rays in accordance with the standard. Implants are presented in a sterile package, under suitable storage conditions, whose stability is guaranteed for **5 years**.



IVenusCon Implants are manufactured with gamma ray resistant materials suitable for medical use, the implants are placed vertically on the **Titanium Rings** on the hanger. There is a **Cower Screw** at the bottom of the hanger. It is designed to be taken with a **1.25 Conical HEX Wrench**, Implant tubes are placed in heat-sealed transparent **Blister and Tyvek** in compliance with medical and gamma standards. It was successfully passed the double-leakage tests with Sealed Tube and Sealed Blister packaging.



WARNING: Never Use Products with Unlocked Safety Locks.





IMPLANT FEATURES





Product Code

L:6

L:8 SLV 3208

L:10 SLV 3210

L:11.5 SLV 3211

L:13 SLV 3213

L:16 SLV 3216





Product Code

2.3

SLV 3706 SLV 3708

SLV 3710 SLV 3711

SLV 3713

SLV 3716







Product Code

SLV 4306

SLV 4308

SLV 4310

SLV 4311

SLV 4313

SLV 4316





2.3

Product Code

SLV 5006

SLV 5008

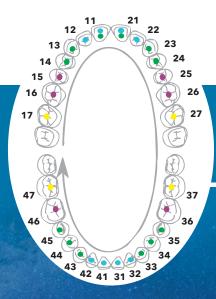
SLV 5010

SLV 5011

SLV 5013

SLV 5016

The figure on the right shows the recommended usage areas of VenusCon Implants according to their



Diameters Leng



CONE PLATFORM MULTI COMP

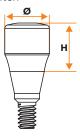
Enhanced superstructure options compatible with all





Narrow

Platform Switch

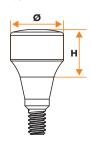


Code	Platform Diameters	Gingival Height (H)
SLV NP101	Ø3.9	2.0mm
SLV NP102	Ø3.9	4.0mm
SLV NP103	Ø3.9	6.0mm



Regular

Platform Switch

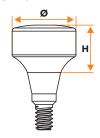


Code	Platform Diameters	Gingival Height (H)
SLV RP104	Ø4.8	2.0mm
SLV RP105	Ø4.8	4.0mm
SLV RP106	Ø4.8	6.0mm



Wide

Platform Switch

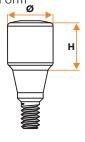


Code	Platform Diameters	Gingival Height (H)
SLV WP107	Ø5.8	2.0mm
SLV WP108	Ø5.8	4.0mm
SLV WP109	Ø5.8	6.0mm



Narrow

Cylindrical Form

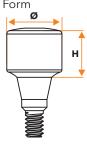


Code	Platform Diameters	Gingival Height (H)
SLV NP110	Ø3.9	4.0mm
SLV NP111	Ø3.9	6.0mm



Regular

Cylindrical Form

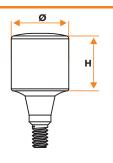


Code	Platform Diameters	Gingival Height (H)
SLV RP112	Ø4.8	4.0mm
SLV RP113	Ø4.8	6.0mm





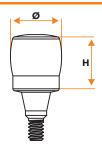
Wide



Code	Platform Diameters	Gingival Height (H)
SLV WP114	Ø5.8	2.0mm
SLV WP115	Ø5.8	4.0mm



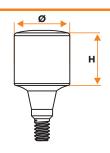
Ti-Base



Code	Platform Diameters	Gingival Height (H)
SLV 30119	Ø4.0	6.0mm
SLV 30120	Ø4.8	6.0mm



PEEK



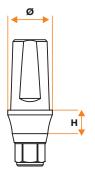
Code	Platform Diameters	Gingival Height (H)
SLV 30121	Ø5.8	6.0mm



Abutment - Gingiva Formers Compatibility Abutment (H) **Gingiva Formers (H)** 1.0mm 2.0mm 4.0mm 2.0/3.0mm 4.0/5.0mm 6.0mm



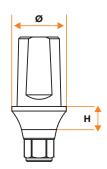
Narrow



	Code	Platform Diameters	Gingival Height (H)
Ī	SLV NP201	Ø3.8	1.0mm
	SLV NP202	Ø3.8	2.0mm
	SLV NP203	Ø3.8	3.0mm
	SLV NP204	Ø3.8	4.0mm
	SLV NP205	Ø3.8	5.0mm

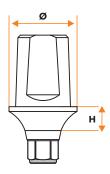


Regular



Code	Platform Diameters	Gingival Height (H)
SLV RP206	Ø4.7	1.0mm
SLV RP207	Ø4.7	2.0mm
SLV RP208	Ø4.7	3.0mm
SLV RP209	Ø4.7	4.0mm
SLV RP210	Ø4.7	5.0mm



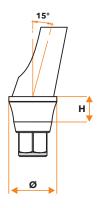


Code	Platform Diameters	Gingival Height (H)
SLV WP211	Ø5.7	1.0mm
SLV WP212	Ø5.7	2.0mm
SLV WP213	Ø5.7	3.0mm
SLV WP214	Ø5.7	4.0mm
SLV WP215	Ø5.7	5.0mm



VENUSCONANGLED ABUTMENT 15°

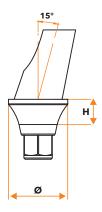
Narrow



Code	Platform Diameters	Gingival Height (H)
SLV NP251	Ø3.8	1.0mm
SLV NP252	Ø3.8	2.0mm
SLV NP253	Ø3.8	3.0mm
SLV NP254	Ø3.8	4.0mm

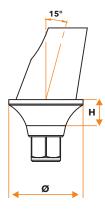


Regular



Code	Platform Diameters	Gingival Height (H)
SLV RP255	Ø4.7	1.0mm
SLV RP256	Ø4.7	2.0mm
SLV RP257	Ø4.7	3.0mm
SLV RP258	Ø4.7	4.0mm



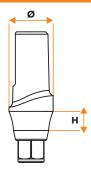


Code	Platform Diameters	Gingival Height (H)
SLV WP259	Ø5.7	1.0mm
SLV WP260	Ø5.7	2.0mm
SLV WP261	Ø5.7	3.0mm
SLV WP262	Ø5.7	4.0mm



VENUSCON ANATOMIC STRAIGHT ABUTMENT

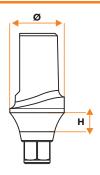
Narrow



Code	Platform Diameters	Gingival Height (H)
SLV NP301	Ø3.8	1.0mm
SLV NP302	Ø3.8	2.0mm
SLV NP303	Ø3.8	3.0mm

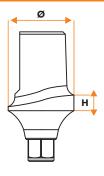


Regular



Code	Platform Diameters	Gingival Height (H)
SLV RP304	Ø4.7	1.0mm
SLV RP305	Ø4.7	2.0mm
SLV RP306	Ø4.7	3.0mm



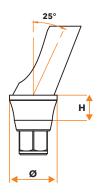


Code	Platform Diameters	Gingival Height (H)
SLV WP307	Ø5.7	1.0mm
SLV WP308	Ø5.7	2.0mm
SLV WP309	Ø5.7	3.0mm



VENUSCONANGLED ABUTMENT 25°

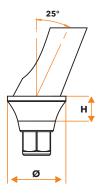
Narrow



Code	Platform Diameters	Gingival Height (H)
SLV NP263	Ø3.8	1.0mm
SLV NP264	Ø3.8	2.0mm
SLV NP265	Ø3.8	3.0mm
SLV NP266	Ø3.8	4.0mm

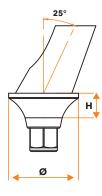


Regular



Code	Platform Diameters	Gingival Height (H)
SLV RP267	Ø4.7	1.0mm
SLV RP268	Ø4.7	2.0mm
SLV RP269	Ø4.7	3.0mm
SLV RP270	Ø4.7	4.0mm



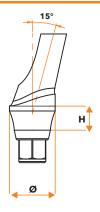


Code	Platform Diameters	Gingival Height (H)
SLV WP271	Ø5.7	1.0mm
SLV WP272	Ø5.7	2.0mm
SLV WP273	Ø5.7	3.0mm
SLV WP274	Ø5.7	4.0mm



VENUSCONANATOMIC ANGLED ABUTMENT 15°

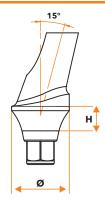
Narrow



Code	Platform Diameters	Gingival Height (H)
SLV NP351	Ø3.8	1.0mm
SLV NP352	Ø3.8	2.0mm
SLV NP353	Ø3.8	3.0mm

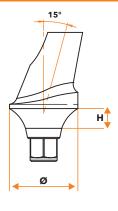


Regular



Code	Platform Diameters	Gingival Height (H)
SLV RP354	Ø4.7	1.0mm
SLV RP355	Ø4.7	2.0mm
SLV RP356	Ø4.7	3.0mm



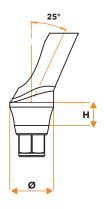


Code	Platform Diameters	Gingival Height (H)
SLV WP357	Ø5.7	1.0mm
SLV WP358	Ø5.7	2.0mm
SLV WP359	Ø5.7	3.0mm



VENUSCONANATOMIC ANGLED ABUTMENT 25°

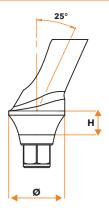
Narrow



Code	Platform Diameters	Gingival Height (H)
SLV NP360	Ø3.8	1.0mm
SLV NP361	Ø3.8	2.0mm
SLV NP362	Ø3.8	3.0mm

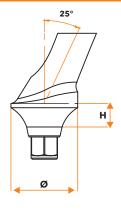


Regular



Code	Platform Diameters	Gingival Height (H)
SLV RP363	Ø4.7	1.0mm
SLV RP364	Ø4.7	2.0mm
SLV RP365	Ø4.7	3.0mm



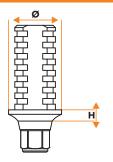


Code	Platform Diameters	Gingival Height (H)
SLV WP366	Ø5.7	1.0mm
SLV WP367	Ø5.7	2.0mm
SLV WP368	Ø5.7	3.0mm





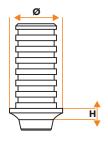
HEX



Code	Platform Diameters	Gingival Height (H)	
SLV 30651	Ø4.7	1.0mm Ti6.	Al4V-ELI
SLV 30653	Ø4.7	1.0mm	_



NO-HEX

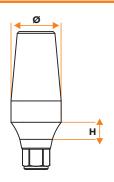


Code	Platform Diameters	Gingival Height (H)	
SLV 30652	Ø4.7	1.0mm	4V-ELI
SLV 30654	Ø4.7	1.0mm	



VenusCon Temporary Abutments are made of **Titanium**; and **PEEK** material for easy shaping. Available with **HEX** and **NO-HEX** options.

VENUSUNIVERSAL STRAIGHT ABUTMENT

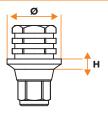


Code	Platform Diameters	Gingival Height (H)
SLV NP001	Ø4.0	2.0mm
SLV RP002	Ø4.7	2.0mm
SLV WP003	Ø5.8	2.0mm



VENUSCON TI-BASE CASTING ABUTMENT

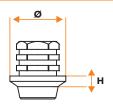
(HEX)



Code	Platform Diameters	Gingival Height (H)
SLV 30850	Ø4.2	0.8mm



(NO-HEX)



Code	Platform Diameters	Gingival Height (H)
SLV 30851	Ø4.2	0.8mm





Burn-Out Casting Cap

SL 30903



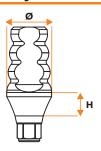
Abutment Screw Ti-Base Casting Abutment is packaged with a **Burn-Out Cap** and two Connection Screws.

It is made of titanium TI6AI4V ELI (Grade 23) materialTi-B





Closed Tray (HEX)

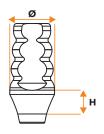


Code	Platform Diameters	Gingival Height (H)
SLV 30100	Ø4.0	2.5mm
SLV 30102	Ø4.8	2.5mm





Closed Tray (NO-HEX)



(Code	Platform Diameters	Gingival Height (H)
	SLV 30101	Ø4.0	2.5mm
	SLV 30103	Ø4.8	2.5mm





Closed Tray Impression Parts are packed with **SLV16000 screws.**



Impression Part Ø4.5 (HEX)

SLV 30112



Impression Part Ø4.5 (NO-HEX)

SLV 30113



Closed Tray Impression Screw

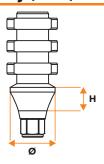
SLV 16004

Impression Part and **SLV 16004 Metric Screw** are used to take measurements with the classical method.





Open Tray (HEX)

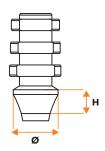


Code	Platform Diameters	Gingival Height (H)
SLV 30108	Ø4.0	2.5mm
SLV 30110	Ø4.8	2.5mm





Open Tray (NO-HEX)

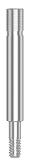


Code	Platform Diameters	Gingival Height (H)
SLV 30109	Ø4.0	2.5mm
SLV 30111	Ø4.8	2.5mm





Open Tray Impression Parts are packed with **SLV16002 screw**.



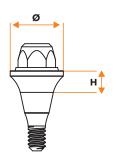
Open Tray Impression Screw

SLV 16002



VENUSCON MULTI UNIT ABUTMENT

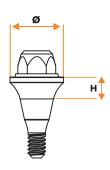
Multi Unit 0° (HEX)



Code	Platform Diameters	Gingival Height (H)	
SLV 30501	Ø5.0	1.0mm	
SLV 30502	Ø5.0	2.0mm	
SLV 30503	Ø5.0	3.0mm	
SLV 30504	Ø5.0	4.0mm	
SLV 30505	Ø5.0	5.0mm	



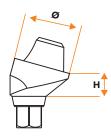
Multi Unit 0° (NO-HEX)



,	Code	Platform Diameters	Gingival Height (H)
	SLV 30506	Ø5.0	1.0mm
	SLV 30507	Ø5.0	2.0mm
	SLV 30508	Ø5.0	3.0mm
	SLV 30509	Ø5.0	4.0mm
	SLV 30510	Ø5.0	5.0mm



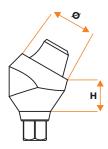
Multi Unit Angled 15°



Code	Platform Diameters	Gingival Height (H)	
SLV 30511	Ø5.0	1.5mm	
SLV 30512	Ø5.0	2.5mm	
SLV 30513	Ø5.0	3.5mm	



Multi Unit Angled 30°



Code	Platform Diameters	Gingival Height (H)	
SLV 30514	Ø5.0	2.5mm	
SLV 30515	Ø5.0	3.5mm	
SLV 30516	Ø5.0	4.5mm	



VENUSCON MULTI UNIT ACCESSORIES (HEX)



Closed Tray Impression Part

SL 30100



Open Tray Impression Part

SL 30102



Titanium Cap

SL 30906



Burn-Out Cap

SL 30901



Ti-Base

SL 30908



Analog

SL 30201



Digital Analog

SL 30205



Konfor Cap

SL 30904



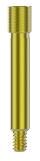
Scanning Part

SL 30910



Implant Connection Screw

SLV 16007



Open Tray Impression Screw

SL 16000



Occlusal Screw

SL 16001

Open Tray Impression Part is packed with **\$L 16000** screw.

Closed Tray Impression Part, Titanium Cap, Burn-Out Cap, Ti-Base and Scanning Part are packed with **SL 16001** Occlusal Screw..



VENUSCON MULTI UNIT ACCESSORIES (NO-HEX)



Closed Tray Impression Part

SL 30101



Open Tray Impression Part

SL 30103



Titanium Cap

SL 30907



Burn-Out Cap

SL 30902



Ti-Base

SL 30909



Analog

SL 30202



Digital Analog

SL 30206



Konfor Cap

SL 30904



Scanning Part

SL 30911



Implant Connection Screw

SLV 16007



Open Tray Impression Screw

SL 16000



Occlusal Screw

SL 16001

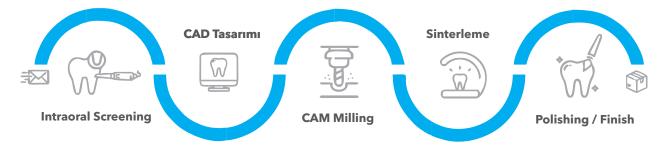
Open Tray Impression Part is packed with **\$L 16000** screw.

Closed Tray Impression Part, Titanium Cap, Burn-Out Cap, Ti-Base and Scanning Part are packed with **SL 16001** Occlusal Screw.





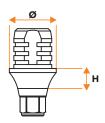
WORKFLOW



You can complete more implant cases in less time, treat more complex cases with confidence, and increase the predictability of the treatment through VenusCon Digital implant workflow.



Ti-Base Cad-Cam (HEX)

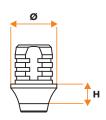


Code	Platform Diameters	Gingival Height (H)
SLV 30801	Ø3.8	1.0mm
SLV 30802	Ø3.8	2.0mm
SLV 30803	Ø3.8	3.0mm
SLV 30804	Ø4.7	1.0mm
SLV 30805	Ø4.7	2.0mm
SLV 30806	Ø4.7	3.0mm





Ti-Base Cad-Cam (NO-HEX)



Code	Platform Diameters	Gingival Height (H)	
SLV 30808	Ø3.8	1.0mm	
SLV 30809	Ø3.8	2.0mm	
SLV 30810	Ø3.8	3.0mm	
SLV 30811	Ø4.7	1.0mm	
SLV 30812	Ø4.7	2.0mm	
SLV 30813	Ø4.7	3.0mm	





Sirona Ti-Base



Code Platform Diameters		Gingival Height (H)	
SLV 30807	Ø4.5	1.0mm	











Premill Abutment SLV P3000



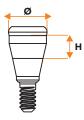
Digital Analog SLV 30202 Scanning Part and Premil Abutment are packaged with **SLV 16000** screws.

Digital Analog is packaged with the **SL 20000** metric screw.





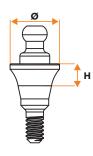
Locator Abutment



Code	Platform Diameters	Gingival Height (H)
SLV 30451	Ø3.86	1.0mm
SLV 30452	Ø3.86	2.0mm
SLV 30453	Ø3.86	3.0mm
SLV 30454	Ø3.86	4.0mm
SLV 30455	Ø3.86	5.0mm



Ball Abutment



Code Platform Diamet		Platform Diameters	Gingival Height (H)
	SLV 30601	Ø4.5	1.0mm
	SLV 30602	Ø4.5	2.0mm
	SLV 30603	Ø4.5	3.0mm
	SLV 30604	Ø4.5	4.0mm
	SLV 30605	Ø4.5	5.0mm





Metal Ring

SL 30905



Ball Abutment Impression Part

SL 30106



Locator Abutment Impression Part

SL 30107

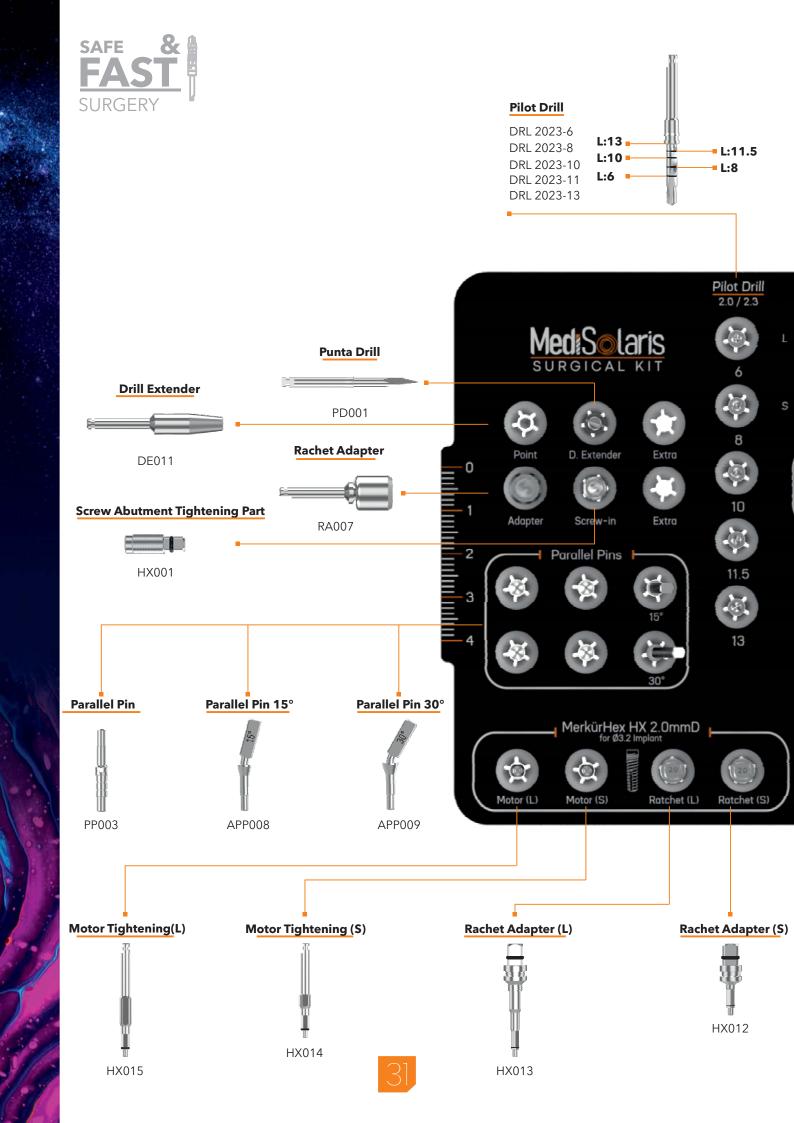


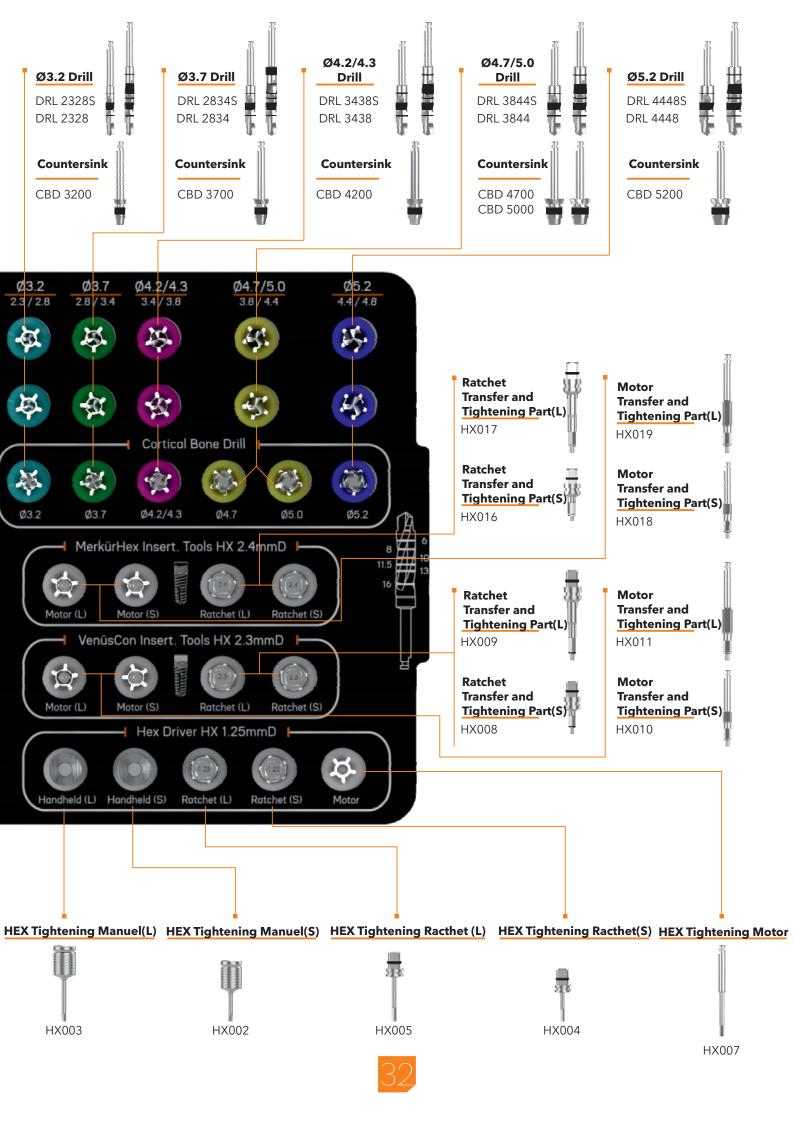


VENUS§

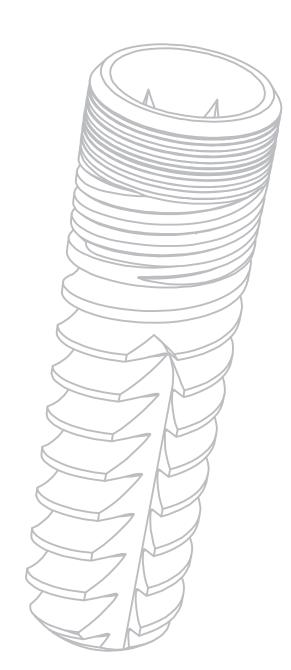
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