

About Implant

Everything You Need to Know

























DENTALIMPLANT SYSTEM

目錄

The Combination of Technology and Healthy Living



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Preface

The dental implant is getting more and more popular in daily dental practice nowadays. Although the successful rate is relatively high, it is still challenging for dentists to perform implant surgery on patients with compromised ridge bone.

The healing process is revolving around the implant surface. A good treated implant surface can offer an environment for fibrin attach, provision matrix formation, bone forming cell (osteoblast) adherence, proliferation, differentiation, and finally, bone formation.

The concept of rough surface emerged from the 90's. Since then, implants with a variety of surface treatment have been launching in the dental market. Among all the implant surface treatments, sandblasted and acid etched (SLA), undoubtedly, is the most popular one. Nevertheless, the chemical residues and particles remain on implant surface during manufacturing processes might affect the healing result.

In 2010, an innovative laser treated implant surface, Biomate implant was launched which carrying a higher oxygen level surface with unique three-dimensional Nano-porous structure, namely "Precision Dimensional Laser (PDL)". The research showed implants with PDL surface treatment came with higher water-soluble protein affinity, higher cell proliferation rate, higher cell density, and higher bone implant contact compared to those with other surface treatments.

In this Q&A, we will not only review the mechanisms of laser surface treatment, but also to review all concepts of design. Meanwhile, the protocols indicate how to use Biomate system in order to receive the best results.

DDS., DMSc Chairman of Biomate IAI

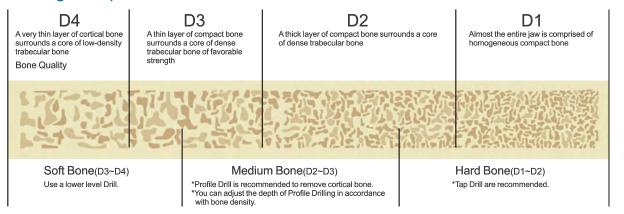




I. How to get the best osseointegration

Recognize Select the Select the Use the drill Be attention to patient's bone suitable implant suitable implant properly the feature of condition **Biomate implant**

1.Recognize patient's bone condition



2. Select the suitable implant system

System	Biom Impla	ate int Syste	Table 1		Biomate Plus Implant System		m	
Size	S	D	R	.D		S	D	
Diameter	3.3	4.1	4.8	5.5	3.5	4.0	4	.5
Length	8/10/12/14	8/10/12/14	8/10/12/14	8/10/12/14	8/10/12/14	8/10/12/14	8/10/12/14	8/10/12/14
Characteristic	(D4.1, I 2. Root Fo 3. Arced R 4. 0.3mm/ 5. Trapezo 6. Self-Ta PDL (Prec treatment Pore, whice move to the The 3D prec	Minor External Expansion Design D4.1, D4.8, D5.5) Root Form Design Arced Root Design D.3mm/0.4 mm Platform Switch Design Frapezoid Thread Design Self-Taping Thread Design L (Precision Dimension Laser) surface atment create micro channel and 3D Te, which lead the bone cell directionally by the to the surface of implant. The 3D provides the best environment for achment and the growth of osteocytes.		1. Single Pore Dimension of Abutment Design (SD) 2. 0.3mm Platform Switch Design 3. 0.7mm vertical smooth surface 4. 0.8mm non-continuous parallel thread 5. Root Form Design 6. Arced Root Design PDL (Precision Dimension Laser) surface treatment create micro channel and 3D Pore, which lead the bone cell directionally move to the surface of implant. The 3D provides the best environment for attachment and the growth of osteocytes.				
Clinical Applicability	2. D3, D4 I 3. Sinus Li 4. The sen	ne early stability is crucial need. B, D4 Bone (Bone condition is very worse) nus Lift ne senior patient mediately loading						



3. Select the suitable implant size

Biomate System

	Dimension Table				
Fixture	Н	imall	RD-Regular		
Diameter	3.3	4.1	4.8	5.5	
Length	1 1	8 10 12 14		3 0 2 4	
Platform	3.3	4.1	4.8	5.5	
Body Diameter(Inside Diameter)	2.8	2.8	3.3	4.0	
Body Diameter(Bottom)	2.7	2.7	3.2	3.8	
Bevel Height	0.3	0.4	0.4	0.4	
Final Drill	2.8 (Blue)	2.8 (Blue)	3.3 (Purple)	4.0 (Orange)	
Counter Sink	/	4.1 (Green)	4.8 (Purple)	5.5 (Orange)	

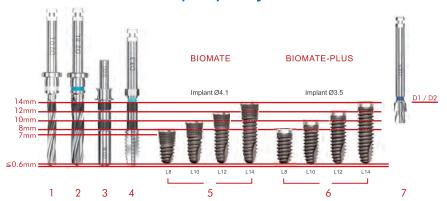
Biomate Plus System

	Dimension Table Unit : mm				
Fixture	SD-Small	SD-Small	SD-Small		
Diameter	3.5	4.0	4.5		
Length	8 10 12 14	8 10 12 14	8 10 12 14		
Platform	3.5 (Dark blue)	4.0 (Pink)	4.5 (Brown)		
Body Diameter(Inside Diameter)	2.8 (Blue)	3.3 (Purple)	4.0 (Orange)		
Body Diameter(Bottom)	2.7	3.2	3.8		
Bevel Height	1.0	1.0	1.0		
Final Drill	2.8 (Blue)	3.3 (Purple)	4.0 (Orange)		
Profile Drill	3.5 (Dark blue)	4.0 (Pink)	4.5 (Brown)		

^{*}Diameter 3.3 is designed for anterior teeth area, not recommended for posterior area.

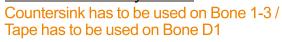


4. Use the drills properly

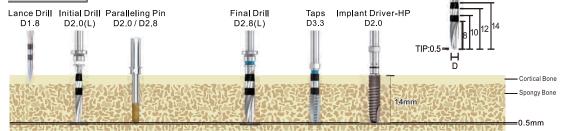


- 1 Initial Drill(L) D2.0mm
- Final Drill(L) D2.8mm corresponds with D4.1mm/D3.5mm fixtures
- Guide Pin D2.8mm
- Tap D3.3mm corresponds with D4.1mm/D3.5mm fixtures
- **6** D4.1mm fixtures with length of 8mm, 10mm, 12mm, 14mm
- 6 D3.5mm fixtures with length of 8mm, 10mm, 12mm, 14mm
- Profile Drill D3.5mm corresponds with D3.5mm fixtures

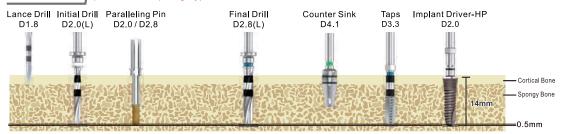
For Biomate System:



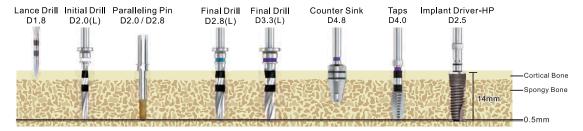
Ø3.3 x L14 (Periodontal flap surgery)



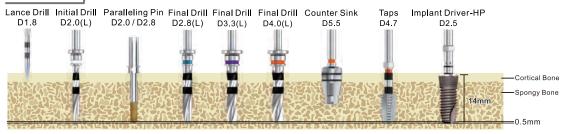
Ø4.1 x L14 (Periodontal flap surgery)



Ø4.8 x L14 (Periodontal flap surgery)



Ø5.5 x L14 (Periodontal flap surgery)



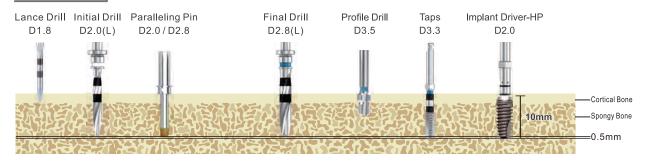
^{*}If you prefer to submerge the implant, we recommend Biomate Implant with 0.5-1.00mm submerged. If you follow up the drill mark, please exceed the mark on initial drill, final drill, countersink in case of 0.5mm-1.00mm submerged. When the fixture can't be fully screwed, or on D1 bone, please use tap.



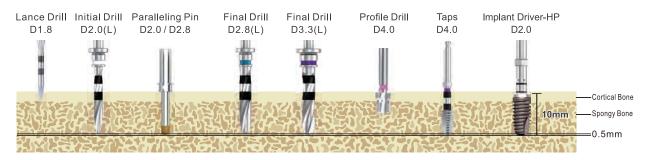
For Biomate Plus System:

Profile has to be used on bone condition at D1-D2 / Tap has to be used on bone condition at D1

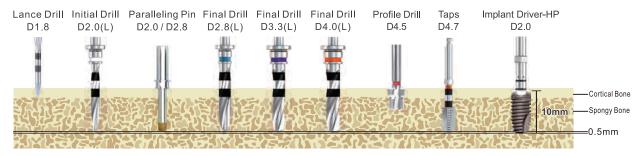
Ø3.5 x L10 (Periodontal flap surgery)



Ø4.0 x L10 / (Periodontal flap surgery)



Ø4.5 x L10 (Periodontal flap surgery)

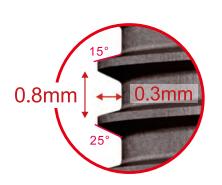


*Recommended:

If you prefer to submerge the implant, we recommend Biomate plus Implant with 0.5mm submerged. If you follow up the drill mark, please exceed the mark on initial drill, final drill and profile drill in case of 0.5mm submerged. When the fixture can't be fully screwed, or on D1 bone, please use tap.

5. Pay attention to the feature of Biomate implants

A.Due to the high energy of laser, Biomate implants are designed with trapezoidal threads, instead of thin-tip threads. This thread design could not only afford a high-energy laser energy, but also provide the asymmetric trapezoid space (the upper part of the thread) squeezing the bone upward and compacting the bone into the space and the trapezoidal thread has a good dispersion effect on the occlusal stress. However, they are not as sharp as most of other threads, such as triangular threads and serrated threads. So, please don't think to use Biomate implant and Biomate-Plus implant to cut the bone.



Drawing	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	A)n	,,,,,	,,,,,
Category	Rectangular thread	Triangular thread	Trapezoidal thread	Serrated thread
圖片				= /00/3

B.Biomate's laser treated surface would be provided 3D pores and micro channel with hemocompatible characteristic, which is beneficial for water soluble proteins adherence, osteocytes proliferation a differentiation. (Biomate's laser treated surface technology can generate micro-nano scale composite orbits, which is very beneficial to the adhesion of water-soluble proteins and the proliferation and differentiation of bone cells.) For this surface structure, in addition to the surface stability, blood supply is the key factor for bone healing process. Excessive stress during insertion might endanger the blood circulation around the implant. If the fixture can't be fully screwed in, please remove the fixture and verify the diameter of the hole. Or please use tap to pre-form the thread. Please never force the fixture to screw into the bone. Using excessive force to screw in the fixture may cause bone necrosis, decrease the blood supply in the surrounding, and ultimately leads to poor ossevintegration. We recommend removing the implant and drilling again with a Tap drill to pre-form the threads to reduce the stress on the implant.







II. How to avoid abutment screw broken

Select the correct implant size

Correct occlusion

Correct screwing torque

1. Select the correct implant size

Correct implant size would be the first concern. The incorrect size of fixture means incorrect abutment. Finally, the abutment screw can't afford bite force properly.

2. Correct Occlusion

The drilling angle will lead the screw not fit to abutment perfectly. When the screw doesn't fit with abutment totally tightly, the bite force will not be evenly distributed, and the screw might broken in long-term use.

3. Correct screwing torque

Use the screw driver with implant motor or torque ratchet to screw the abutment with recommended torque maximum 30 Ncm. Using excessive force to screw in the abutment may distort the screw and may also cause the screw to break directly.

III. How to avoid bone loss

Use Counter Sink,
ProfileDrill,
Taps properly

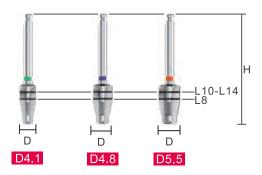
The correct torque

1. Be sure to use Counter Sink, Profile Drill and Taps properly.

A-1 For Biomate Implant System (Minor External Expansion Design):

Countersink has to be used on bone under the skeletal conditions of D1~D3. **Use to trim** the cortical bone with rotation speed 1,200rpm, torque 20Ncm, feed water; Each Biomate implant diameter corresponds to different color of counter sink. please drill to different laser marking lines according to different implant length when using. For L8mm length implants, please drill to the first laser marking line from bottom to top, and for L10 / L12/L14mm length implants to the second laser marking line from bottom to top, which it could reduce the stress effectively during implantation stress. See the Table 1 as below.

Counter Sink Unit : mm



Name	Diameter (D)	Height (H)	Catalog No.	Fixture Ø
	D4.1	29	3AA-014	4.1
Counter Sink	D4.8	29	3AA-015	4.8
	D5.5	29	3AA-016	5.5

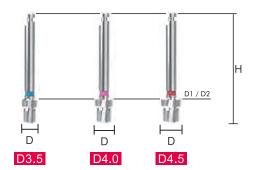
- Used to trim the cortical bone with rotation speed 1,200rpm, torque 20Ncm, feed water; each drill corresponds to different diameters of fixtures
- Drill to the second laser mark for L10-L14 Implant or the first for L8mm Implant
- Counter Sink D4.1 is used after Final Drill D2.8
- Counter Sink D4.8 is used after Final Drill D3.3
- Counter Sink D5.5 is used after Final Drill D4.0

A-2 For Biomate Plus Implant System:

Profile drill has to be used on bone under the skeletal conditions of D1~D2. **Use to trim the cortical bone with rotation speed 1.200rpm, torque 20Ncm, feed water**, Each Biomate Plus Implant diameter corresponds to different color of profile drill. Please drilling the Profile Drill align the bone surface completely. See the Table 2 as below.

Profile Drill

Unit: mm



Name	Diameter (D)	Height(H)	Catalog No.	Fixture Ø
	D3.5	24	3AA-065	3.5
Profile Drill	D4.0	24	3AA-066	4.0
	D4.5	24	3AA-067	4.5

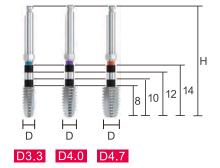
- Used to trim the cortical bone with rotation speed 1,200rpm, torque 20Ncm, feed water; each drill corresponds to different diameters of fixtures
- Profile Drill
- Profile Drill D3.5 is used after Final Drill D2.8
- Profile Drill D4.0 is used after Final Drill D3.3
- Profile Drill D4.5 is used after Final Drill D4.0

A-3 For Biomate and Biomate Plus Implant System:

In order to reduce the stress of the submerged implant, please be sure to use Taps drill to pre-formed threads on D1 or harder bone. Each Biomate / Biomate-Plus implant must drill in accordance with different diameters of taps. **Used with rotation speed set at 20rpm, torque 35Ncm**; set the implant motors to reversed rotation to withdraw the instrument after Tapping. See the table 3 as below.

Taps

Unit: mm



Name	Diameter (D)	Height (H)	Catalog No.	Fixture Ø
	D3.3	29	3AA-017	3.5
Taps	D4.0	29	3AA-018	4.0
	D4.7	29	3AA-019	4.5

- Used on D1 bone to create threads inside the hole; each drill corresponds to different diameters of fixtures
- Used with rotation speed set at 20 rpm, torque 35 Ncm; set the implant motors to reversed rotation to withdraw the instrument after drilling
- Tap D3.3 is used after drilling with Final Drill D2.8 and Counter Sink D4.1
- Tap D4.0 is used after drilling with Final Drill D3.3 / Profile Drill D4.0
- Tap D4.7 is used after drilling with Final Drill D4.0/Counter Sink D5.5

2. Insert implant with correct torque

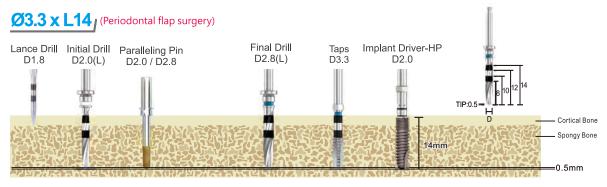
Please never use excessive force to screw fixture with implant submerged on the bone. Using excessive force to screw the fixture on to the bone may damage the bone and cause bone infarction due to the excessive stress and lack of blood. Please insert the implant with a torque of 35Ncm. The torque value should not exceed 35Ncm. In the fixture can't be fully screwed with a torque of 35 Ncm, please be careful not to use a high torque to screw the fixture and verify the diameter of the hole. Please check whether the depth of the hole is sufficient after reversing the implant. Or please use taps drill pins to pre-form the threads at 20rpm / 35Ncm. Otherwise, the fixture will gain too much stress and damage the micro-Channel on the surface which makes the lack of blood. Finally, this kind of incorrect installation will cause bone loss or surgical failure.



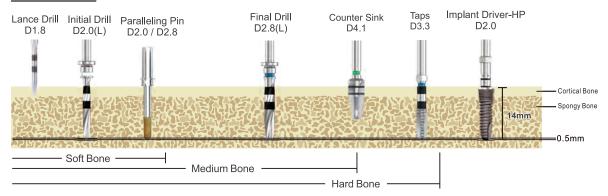
IV. How to do immediate extraction /Immediate Loading

- Follow up Biomate drill sequence properly.
- Use counter sink and tap properly
- 1. Follow up Biomate drill sequence properly. Please follow up our drill sequence. Don't skip final drill at each one of bone conditions; otherwise, the stress will be too high on the expansion section and might cause bone loss.

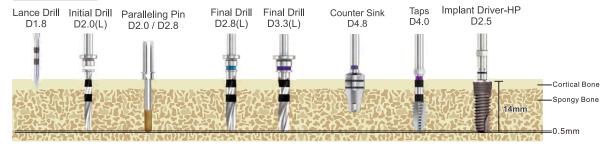
For Biomate System:



Ø4.1 x L14 (Periodontal flap surgery)

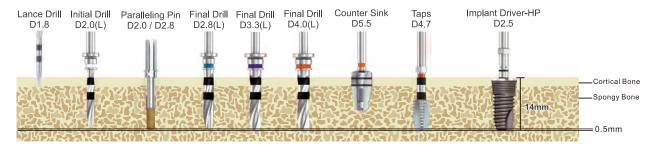


Ø4.8 x L14 (Periodontal flap surgery)





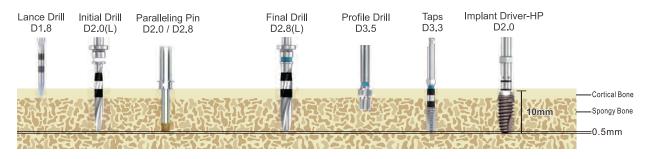
Ø5.5 x L14 (Periodontal flap surgery)



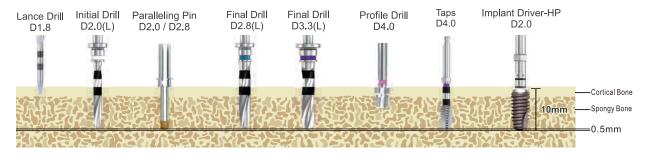
For Biomate Plus System:

Profile has to be used on bone condition at D1-D2 / Taps has to be used on bone condition at D1-D2

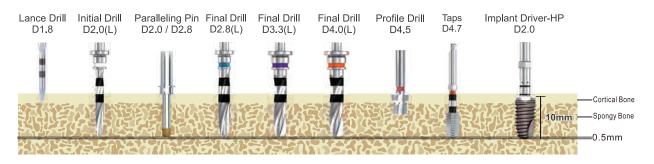
Ø3.5 x L10 (Periodontal flap surgery)



Ø4.0 x L10 (Periodontal flap surgery)



Ø4.5 x L10 (Periodontal flap surgery)





2. Use counter sink and tap properly

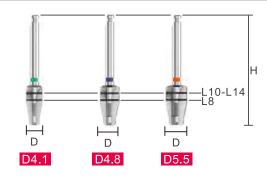
2-1. Bone condition is at D3 or D4:

If the extraction wound is bigger than 4.8, you can skip final drill and counter sink to plant diameter 4.8 implant, or the extraction wound is bigger than 5.5, you can skip final drill and counter sink to plant diameter 5.5 implant.

2-2. Bone condition is at D1 or D2:

No matter the extraction wound is big or not, we strongly suggest using final drill and counter sink (Biomate system) or profile drill (Biomate Plus system). If doctors skip using these drills, we worry that the stress can't be distributed even and cause bone loss.

Counter Sink Unit : mm

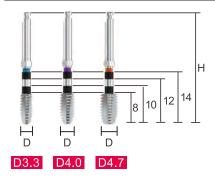


Name	Diameter (D)	Height (H)	Catalog No.	Fixture Ø
	D4.1	29	3AA-014	4.1
Counter Sink	D4.8	29	3AA-015	4.8
	D5.5	29	3AA-016	5.5

- Used to trim the cortical bone with rotation speed 1,200rpm, torque 20Ncm, feed water; each drill corresponds to different diameters of fixtures
- Drill to the second laser mark for L10-L14 Implant or the first for L8mm Implant
- Counter Sink D4.1 is used after Final Drill D2.8
- Counter Sink D4.8 is used after Final Drill D3.3
- Counter Sink D5.5 is used after Final Drill D4.0

Tap

Unit: mm



Name	Diameter (D)	Height (H)	Catalog No.	Fixture Ø
	D3.3	29	3AA-017	3.5
Тар	D4.0	29	3AA-018	4.0
	D4.7	29	3AA-019	4.5

- Used on D1 bone to create threads inside the hole; each drill corresponds to different diameters of fixtures
- Used with rotation speed set at 20rpm,torque 35Ncm; set the implant motors to reversed rotation to withdraw the instrument after drilling
- Taps D3.3 is used after drilling with Final Drill D2.8 and Counter Sink D4.1
- Taps D4.0 is used after drilling with Final Drill D3.3 and Counter Sink D4.0
- Taps D4.7 is used after drilling with Final Drill D4.0 and Counter Sink D5.5

*One condition would be excepted.

When the extraction wound is too big, actually doctor just puts implant onto the wound; no drill is needed.



- Q1.0 Biomate Laser Treatment applies what kind of laser?
- A1.0 Biomate applies solid state laser.
- Q2.0 Please advise the procedure of your surface treatment:
- A2.0 After thorough cleaning of the machined implant surface with Ultrasonic Washing System, laser emission with high power and density is focused on and ablates the implant surface. The implant will rotate 360 degree with the surface ablated only once, forming regularity porous texture on the implant surface.

After such procedure, the implant is then sent for cleaning.



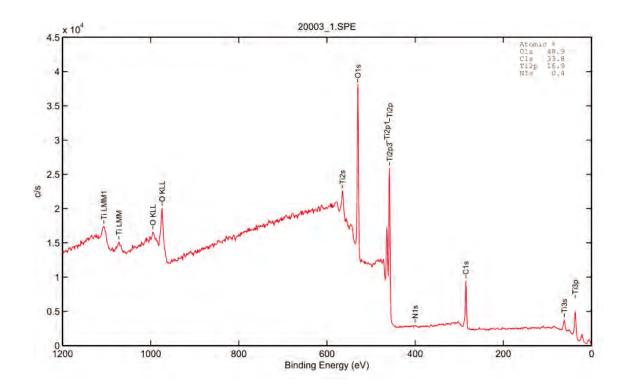
Remark: Please refer to the following website- https://youtu.be/RFbGDZkJ i4

- Q3.0 What is the theological base of Biomate laser surface treatment? Do you have any academic evidence for reference?
- A3.0 Biomate laser surface treatment is a type of hot working technique, which applies high energy density laser (up to 1700°C), focusing on the metal surface to fuse and evaporate the surface with the heat. With adjusted laser parameter, the regularity porous texture is formed due to sudden evaporation or fusion by the ablation of laser, and thus such laser treatment is defined as subtraction-type laser treatment. Biomate's patent laser technique can form unique 3D pores with micro-nano texture on implant surface, which is designed to become an environment suitable for the growth of osteocytes. Such environment has also been proven in many experiments to effectively increase the density of the growth and adhesion of osteocytes, thus improve osseointegration.



- Q4.0 "Is titanium metal prone to phase-transformation after laser surface treatment? "Research physicians noted that different elements in titanium alloy react differently to heat. This reaction may cause uneven surface on the titanium alloy, thus effecting long-term osseointegration. We would like to know if your company has done research to avoid such concern.
- A4.0 Biomate dental implant uses Grade IV titanium that comprises above 99% Titanium, thus, it is not susceptible to phase-transformation. We have done a research to see if there is phase-transformation after laser surface treatment.

From our research result, the surface elements contain Ti, N, O, C. We only get TiO2 from the analysis of chemical bond



Spectrum processing:

Peak possibly omitted : 6.340 keV

Processing option: All elements analyzed (Normalised) Number of iterations = 1

Standard:

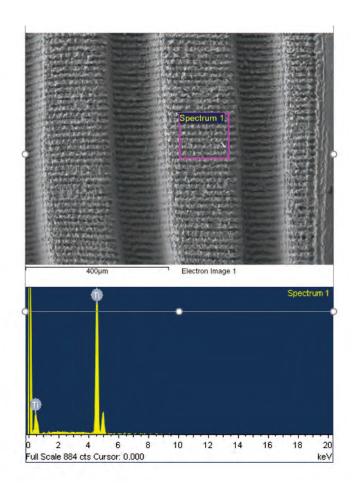
Totals

Ti Ti 1-Jun-1999 12:00 AM

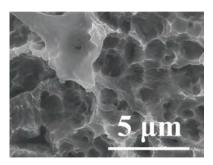
Element	Weight%	Atomic%
Ţį,Κ	100.00	100.00

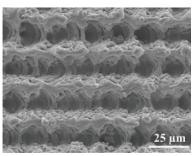
100.00

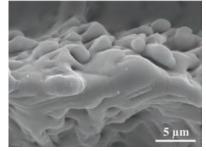
Pure Titanium



By high energy of laser emission, the irradiated area of the titanium surface will be punched to be a micro size of pore which is linear arranged. And some metal will be melted to form a nano size of pore. The micro-nano complex texture with averagely 13µm depth and 10-20 µm width, effectively promotes osteocytes to Osseo integrate with the implant. The fatigue test of Biomate surface treated implant shows an equivalent strength and durability to that of SLA™ treated implant. The titanium alloy you mentioned contains aluminum and vanadium, which will be altered by heat.



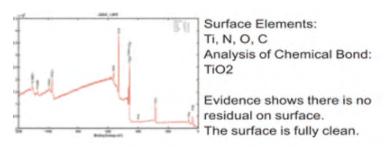






Q5.0 What is the feature of Biomate Laser Surface Treatment?

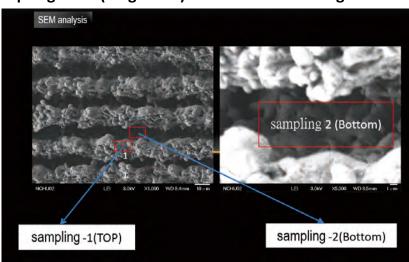
A5.0 1. Cleanliness: Biomate implant modifies the implant surface with laser, with no toxic residue, unlike traditional SLA surface treatment which risk having sand and acid residue.



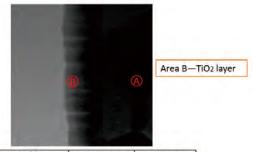
- 2. Precise: With adjusted laser parameter and thus each implant after laser surface treatment are 100% cohesive. The roughness of surface can be handled very precisely by Biomate laser technology.
- 3. 3D micro-Nano texture: Patented Precision Dimensional Laser (PDL) creates microchannels containing micro-nano 3D complexes. Microchannels with micronano 3D pores texture and direct bone cell growth on the implant surface. This design forms an environment suitable for the growth of osteocytes. Also, this environment increases the density of the growth and adhesion of osteocytes. This has been proven in many experiments, effectively improving osseointegration.
- 4. Hemocompatibility: After laser treatment, titanium atom will merge with oxygen atom in the air and form titanium oxide layer, which has been proven to facilitate hemocompatibility and increase the efficiency of osseointegration
- ※ 5-year follow-up study by the Swedish company Brandmark Integration AB, laser surface treatment has shown success rate of bone integration about 99.3%.
- X The 3-year follow up clinical condition of Biomate shows 99% success rate.
- Q6.0 Does your laser surface treatment combine any other technique to increase the roughness and porous on the surface of the implant?
- A6.0 By the application of patent precision laser parameter, PDL™ Surface Treatment can effectively control the roughness and the porous size on the surface of the implant without combining any other technique. Therefore, PDL™ Laser Surface Treatment can form roughness and porous size on the implant surface matching that of academic research data for outstanding osseointegration with non-residue and non-contact luminous energy to pursue better bone healing effect.

- Q7.0 Can oxide layer on the implant surface optimize biocompatibility?
- A7.0 The discovery of Dr. Brånemark in 1960s shows that titanium possesses the effect of osseointegration with human bone. Studies show that the oxide layer on the titanium surface can optimize the adhesion and regeneration of blood and osteocytes; such argument is then proven by many scholars with further research.
- Q7.1 Is the oxide layer on Biomate implant surface formed by laser?
- A7.1 Yes. When irradiated by laser emission, the irradiated area of the titanium surface will fuse or evaporate to integrate with the oxygen atom in the air and form a titanium oxide layer with the thickness decided by the adjustment of laser parameter.
- Q7.2 How is the thickness of oxide layer formed on Biomate fixture?
- A7.2 We have measured the thickness of oxygen layers.

Top of groove (ridge area): 110nm Bottom of groove: 45nm



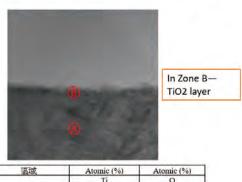




區域	Atomic (%)	Atomic (%)
	Ti	0
A	93.01	6.99
В	44.75	55.25

Much thicker oxidized layer (uncrystalized amorphous TiO2) The area thickness of whole Ji O2 about 110nm.
 Much larger Ticrystal

Energy Disperse spectrometry (EDS)



區域	Atomic (%)	Atomic (%)		
70,00	Ti	0		
A	94.3	5.7		
В	34.1	65.9		

Amorphous TiO2 layer and 20nm granulized Ti crystal in the laser treated surface, about 20nm, whole thickness of this layer is abut 45 nm •



- Q7.3 Please explain the principle of the abundant formation of oxide layer on PDL™ treated Biomate Implant surface.
- A7.3 Biomate Implant System applies high active, medical grade IV pure titanium imported from Carpenter Company in the US. An oxide layer with the thickness of 5 nanometer called TiO2 is formed on the surface of the pure titanium when contacting oxygen, possessing following features:
 - 1. A TiO2 layer with anatase texture can effectively increase the adhesion of protein and decrease the proliferation of fiber tissue.
 - 2. The TiO2 layer can help to improve the connection between the bone and the implanted material and to help the proliferation of hydroxyapatite in SBF.
 - 3. Prevent the liberation of metal ion (The liberation of metal ion is characteristic of titanium alloy for it contains vanadium and aluminum. Such liberation of vanadium and aluminum ion will be harmful to human body when implanted in corrosive environment. Therefore, application of pure titanium can avoid the concern of liberation of poisonous ion).
 - 4. Researchers discovered that the increase of the oxide layer thickness can facilitate hemocompatibility and biocompatibility, thus effect growth of cell. Although TiO2 is beneficial for implant, the natural formed oxide layer with the average 5 nanometer is not enough to help osseointegration. Biomate's patent laser surface treatment can increase the roughness of the implant surface while a thicker oxide layer is formed. It is mainly due to the heat of the focused laser emission causing transient liquefaction of the ti-surface, making it easier to combine with oxide molecule, thus thicken the oxide layer.

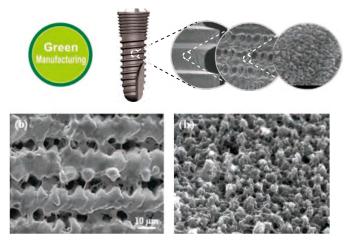
Q8.0 Please explain PDL™ Surface Treatment?

A8.0 PDL™ Surface Treatment (Precision Dimension Laser) applies precise parametric design and through high efficacy laser luminous energy to strike qualitative micro-nano, complex 3D pores that greatly increase the contact surface area of the bone and the implant, optimizes the effect of cell proliferation and osseointegration.

Better Biocompatibility

PDL™ laser treated implant surface possesses complex micro-nano texture; such characteristic can help increase the stability and adhesion of cell, effectively accelerate bone proliferation and osseointegration...

The 3D texture formed by the innovative PDL™ Surface Treatment Technique provides a wide contact area for the adherence and growth of osteocytes.



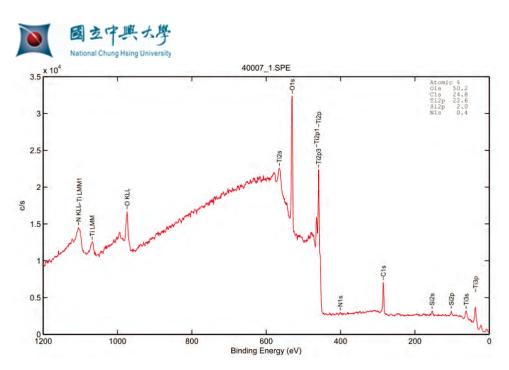


Q8.1 What are the assets of PDL^{TM} Laser Surface Treatment? A8.1

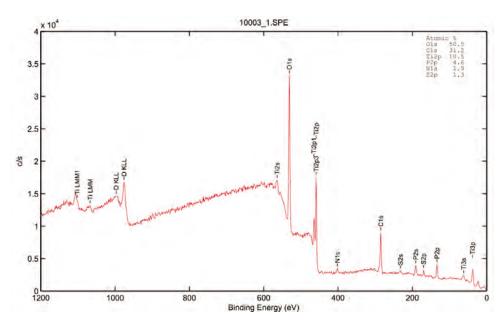
Phase	Description	Picture
Osseointegration	The complex micro-nano 3D pores of BIOMATE-PLUS fixture surface can effectively help to: Optimize the adhesion and growth of osteocytes Accelerate the healing of wound Improve osseointegration	SEM SOOC & T KIN Cell
Contact Area	PDL®(Precision Dimensions Laser) Surface Treatment applies precise parametric design and through high efficacy laser luminous energy to strike qualitative micro-nano, complex 3D texture that help increase the contact surface area of the bone and fixture, optimizes the effect of cell proliferation and osseointegration.	
Cell Adhesion	The nano structure surface of multiple micro channel created by PDL® technique can help the adhesion of hydrophilic protein like cells, fibrin and so on. There is special metal solution and molecular arrangement in the micro-nano pore. When osteocyte enters the pore, it can stably adhere to the nano structure, plus with the special pore size of Biomate which can accelerate the cells extension and differential, it can significantly improve the osseointegration (the red arrow in the picture shows the cell. SEM report shows the PDL® treated surface is highly suitable for the growth of osteocytes).	\$3400 15 GAV 10 Gmm x3 GVX SE
Hemocompatibility	Proven by experiment, the complex micro-nano texture of BIOMATE-PLUS fixture surface has the best hemocompatibility, which absorbs blood rapidly to the fixture surface during implantation. This feature can effectively accelerate bone regeneration and osseointegration.	O* 1.5mm
Cleanliness	Unlike the traditional SLA surface treatment that risk of sand & acidic residue after treatment, PDL® surface treatment modifies the fixture surface with laser that does not leave any toxic residue.	Surface Elements: Ti, N, O, C Analysis of Chemical Bond: TiO2 Evidence shows there is no residual on surface. The surface is fully clean.



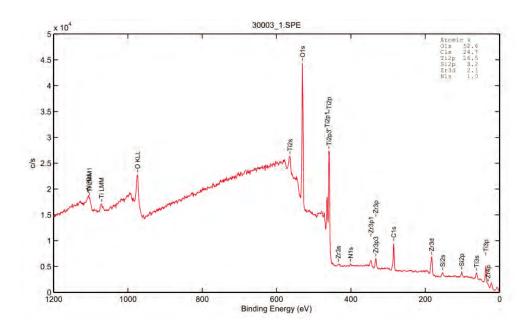
- Q8.2 How could you demonstrate your surface is clean without any risk of residue.
- A8.2 National Chung Hsing University has conducted a research to compare the difference of surface cleanliness among branded implants. We demonstrate Biomate implant's surface is pure clean.



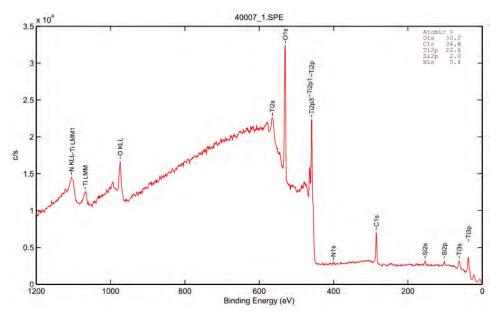
Biomate; laser treated; Grade IV pure titanium Contains Ti, N, O, C



Nobel Biocare; TiUnite treated, Contains Ti, P, N, S, O, C



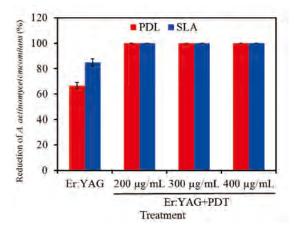
Straumann SLA treated; Ti-Zr Alloy Contains Ti, Si, Zr, N, O, C



X'ive; Grade II pure titanium; SLA treated Contains Ti, Si, N, O, C



- Q8.3 Based on your information, PSL laser surface treatment will create a unique surface, complex 3D texture, that help increase the contact surface area of the bone fixture, optimizes the effect of cell proliferation and osseointegration. Does it mean when the implant is inflamed, the complex 3D texture will cause more bacterial than the other implant? And does it also mean laser surface would be harder to clean the bacterial?
- A8.3 Chung Shan University has conducted a research to find that bacterial on complex structure can be cleaned by the combination therapy of Er:YAG Laser and aPDT systemby. The combination therapy of Er:YAG Laser and aPDT system can clean deeply and efficiently into microchannels for both SLA and PDL surface without altering the surface architecture, could be a useful cleaning method for peri-implantitis therapy especially for a nano microtextured surface.



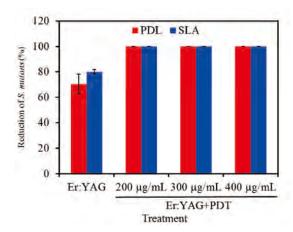


Fig. The antimicrobial effectiveness of Er:YAG, methylene blue (MB)-mediated PDT, and the combination of Er:YAG + MB-mediated PDT against the reduction of A. actinomycetemcomitans and S. mutans seeded on PDL and SLA implant surfaces for 24 h.

In addtion, this research finds that bacterial, A. actinomycetemcomitans, attached onto the deep site of the complex 3D structure is no big difference between 4 hours and 48 hours. It also shows that A. actinomycetemcomitans doesn't attached on the laser surface as many as on SLA surface. A. actinomycetemcomitans cause peri-implantitis.

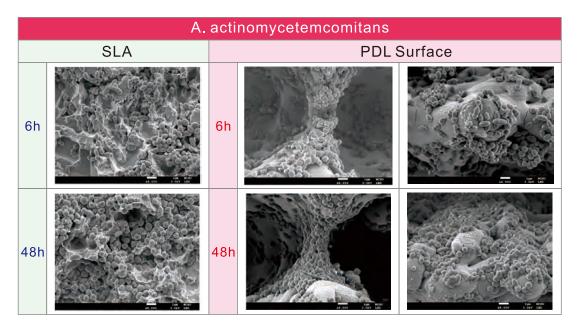
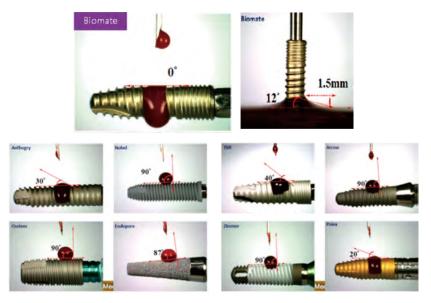


Fig. Scanning electron micrographs of Laser-treated Ti surfaces and SLA-treated Ti surfaces after seeding with A. actinomycetemcomitans for 6 and 48 h.

- Q8.4 All users of dental implant expect outstanding hemocompatibility, thus, please provide some reference on Biomate implant.
- A8.4 Biomate can set different parameters to characterize the material as super hydrophilic, hydrophilic or hydrophobic. Biomate's implant, proven by the research of Research Center of Taipei Medical University on the comparison of different implant brands, is super hydrophilic (the contact angle shows zero degree when dripping blood on the implant).



Remark: Reference: https://www.youtube.com/watch?v=IW2XoZ0RHyc



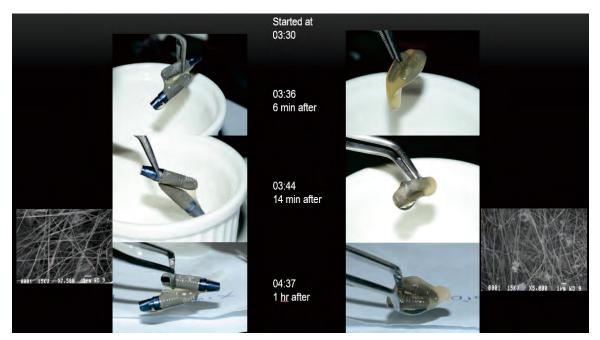
- Q8.5 Does hydrophilicity of the fixture fall accompanied with time passing? or would it be the reason to affect the successful osseointegration of bone cells?
- A8.5 1. After sterilization, the hydrophilicity of fixture will be deducted and recessed when time passes.
 - 2. Biomate implant generates the best effect of osseointegration. As a result of below factors, the effect of osseointegration will not be affected by the deduction and recession of hydrophilicity.
 - A. Laser produces an oxide layer called TiO2, which is formed on the surface of the pure titanium when contacting oxygen. The TiO2 layer with anatase texture can effectively increase the adhesion of protein and decreases the proliferation of fiber tissue. Meanwhile, the TiO2 layer can help to improve the connection between the bone and the implanted material and to help to improve the proliferation of hydroxyapatite in SBF.
 - B. Laser produces a directional pores in the surface of implant. The directional pores can successfully guide the cells into the holes then successfully climb and growth.
 - C. Laser produces the complex micro-Nano surface, which can help the adherence of cell, cellulose and protein. When osteocyte enters the micro-Nano pore, it not only stably adheres to the Nano structure of the pore, but obtains the best extension-reaching, then gradually making improvement of osseointegration.
- Q8.6 Why kinds of rations to explain Biomate implant is a unique implant for some special bone conditions?
- A8.6 Actually, when Biomate developed implant 10 years ago, Biomate knew that so many implants already have been in the market. Therefore, Biomate decided not to develop a "me too" product. Biomate hoped to develop a new implant to help doctors reduce the risks of implantation surgery when patients with poor bone condition.

National Industrial Technology Institute assists Biomate to apply laser to create a unique structure of implant surface which makes the best osseointegration. Overall, Biomate implant is the best choice for: 1, senior people with poor bone condition, 2 patients with three traits: a. Oral cavity inflammation, b. Low bone density C. Short and narrow bone ridge.

The structure of Biomate implant possesses two unique characters, which makes Biomate implant is the best choice for these special bone conditions described as above.

First, the high laser energy created a high oxidized surface which achieved high hemocompatibility offering an environment for fibrin attach then benefit for provisional matrix forming that is important for the early stage. The research shows that laser surface could make rapid formation of a fibrin clot than the SLA surface, which results from the activation of the coaqulation cascade via both the extrinsic and the intrinsic pathways

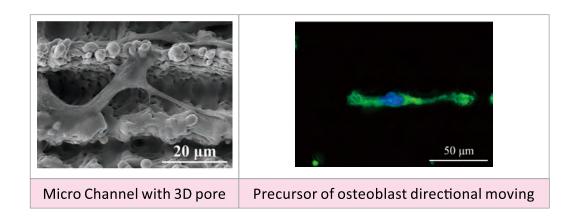




Xive Implant

Biomate Implant

Second, our patented Precision Dimensional Laser (PDL) creates unique microchannel with micro-nano complex 3D pore. The microchannel induced the precursor of osteoblast directional moving onto the implant surface faster than any other implant with different surface treatment, Finally, the micro-nano 3D pore improving the efficiency of osteoblast adherence, proliferation, differentiation, and finally, bone formation.



Because of the microchannel with micro-nano complex 3D pore and high oxidized layer, even on the compromised bone ridge, the bone cells can be effectively guided to adhere, proliferate and differentiate to accelerate the osseointegration. Hence, the clinic successful rate has been enhanced as well as alveolar bone height can maintain for a long time.





Cell attachment on the machinery surface.

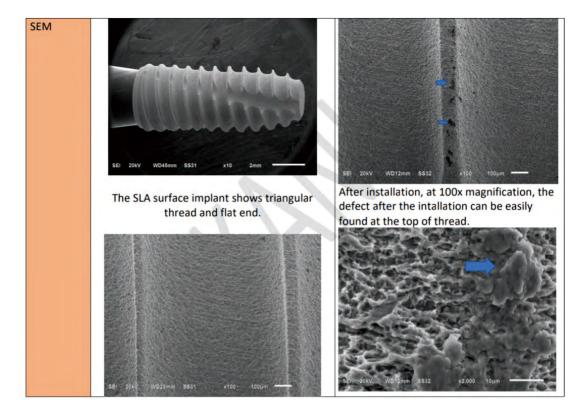


Cell attachment on the SLA surface.

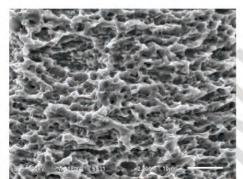


Cell attachment on LASER surface.

- Q8.7 The current consensus is that a rougher surface accelerates osseointegration, which is one of the main parameters for implant success. Therefore, numerous methods are being used to alter the surface topography of titanium implants. These include machining, abrasive blasting, acid-etching, anodization and laser treating or a combination of these. PDL laser treatment creates a complex 3D (micro-nano) structure with micro channel. Comparing to the other treated implant surface, nano-roughness promotes osteoblast adhesion and bone morphogenic protein activity. But I am wondering if the macro-nano roughness is easy to be damaged at the high torque force?
- A8.7 According to SEM study conducted by Mahidol University, Biomate plus presented only few damage over the implant. The damage could be found as chipping, pit, and flattening. SLA implant presented pit, flattening ad fused surface in larger amount compare to Biomate Plus. The defect could be easily found especially in apical thread corrrresponding to self-tapping design. Biomate plus surface did not present the sharp asperities in micro level, therefore this might be the reason why it had minimal surface alteration and more durable properties. Therefore, the macro-nanoroughness is not easy to be damaged at the high torque force. It demonstrate that the constructure of surface is very firm.

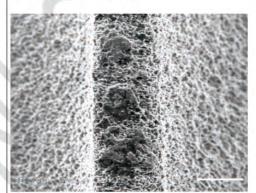


At 100x magnification, the SLA surface shows homogeneous cobweb-like pattern.

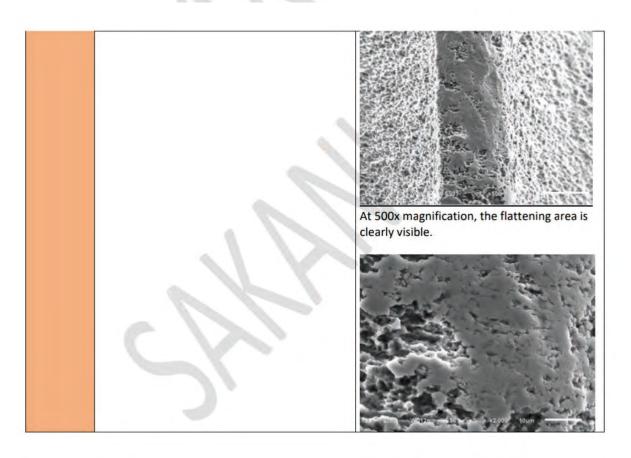


At 2000x magnification, the surface presents multiple sharp spikes and round pits spreading in a random pattern.

At 2000x magnification, the spikes were compressed into flat area.



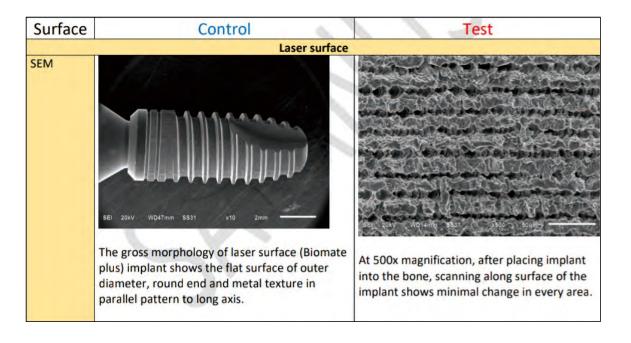
At 500x magnification, the pit, pore and elevation are found at the top of thread.

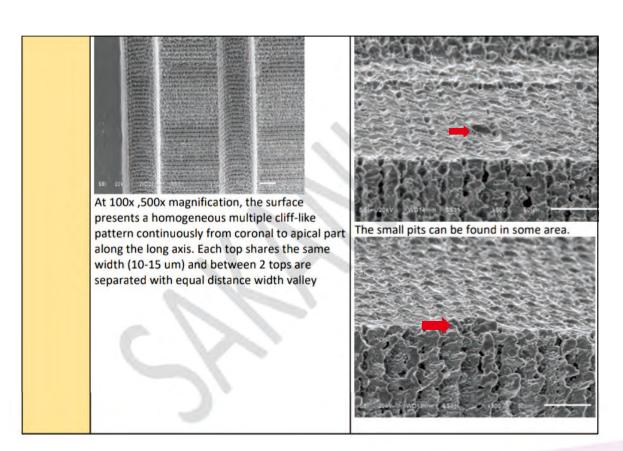


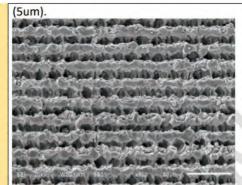


Q&A

I. Regarding Surface Treatment

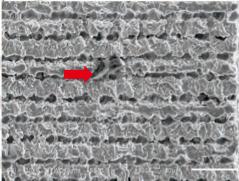




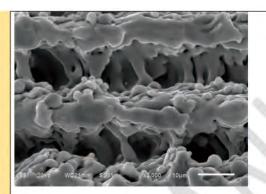


At 500x magnification, the surface shows homogeneous pattern which the top shows mild roughness formed with pebble shape area, the cliff shows multiple pebble-like and the bridge connects between each hill, and the deepest part of valley could not be reach with SEM.

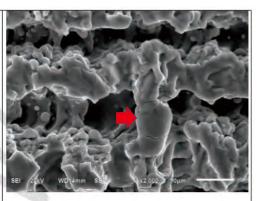
The crest of thread shows chipping but underneath those area, the roughness pattern still can be found.



The chipping also can be found in flat area which disrupts the continuity of the pattern and the titanium surface seems a little bit more flattening.



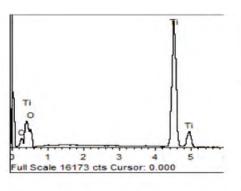
At 2000x magnification, the image confirms the minimal knobby-like pattern at the top and multiple pebble on the cliff. The pebbles at the top seem larger and more elliptical, while the pebbles on the cliff seem smaller and round. In addition, the small crack line can be found generally at the top.

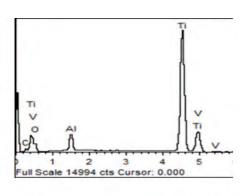


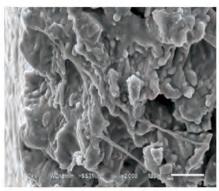
In some area, the bridging part is shown at the top which is unusually seen in control group. This may emphasize that the titanium was abraded during insertion then the bridge area came to the top.

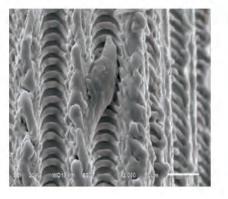


- Q 8.8 What can we demonstrate that Biomate laser surface treatment can enhance the osseointegration
- A8.8 Mohido University conducted a study, which was designed to analyze the surface chemistry and topography of laser-irradiated Titanium implants and to evaluate the cell morphology and cell adhesion of Human Fetal Osteoblasts(HFOB) that were seeded on the implants. HFOB cell adhesion is possible after 48 hours in laser-irradiated titanium. However, the reason for the lack of cell maturity and cell adhesion in Biohorizon samples is still unknown. The presence of organic particles on the BIOMATE implants did not deter cell maturation in this in-vitro experiment.







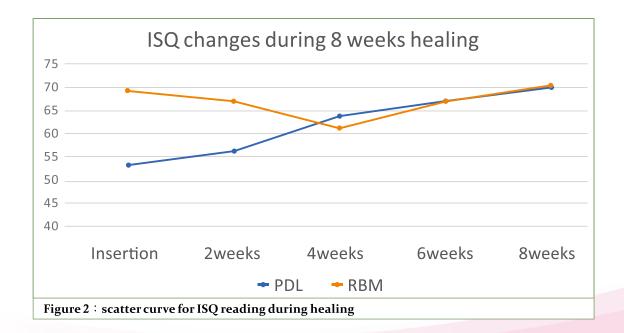


BIOMATE: EDS and HFOB under SEM

BIOHORIZON: EDS and HFOB under SEM

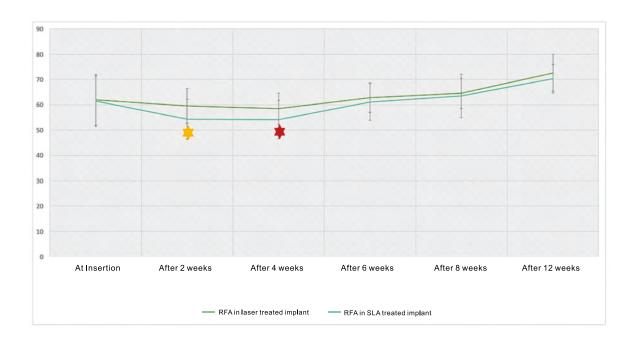


- Q 8.9 Prof. Dr. Amr's paper, "The impact of PDL versus RBM implant surface treatment on implant stability during healing: A preliminary clinical study," shows implant stability dip from week 2-6 while PDL implants show gradual increase in stability throughout the healing phase. Despite the significant difference in ISQ value at insertion time both implants reach similar ISQ value at week 8.
 - 1. The mean ISQ values at time of insertion were 68.4±5.2 and 53.8±3.3 for RBM and PDL implants respectively.
 - 2. At week 4, RBM implant showed significant decrease in ISQ values 62.6±5.6, while PDL showed significant increase 63.5±4.1.
 - 3. At week 6, ISQ in both groups showed Signiant increase 66.2±4.7 and 66.7±3.9 for RBM and PDL
 - 4. at week 8 respectively and 70.1±3.4 and 70.9±5.4 at week 8 for RBM and PDL implants respectively Please explain why Biomate's the stability is increasing, but RBM's stability decrease at week 4 and then increase.
- A8.9 Biomate's laser treated surface is equipped with 3D pores and micro channel, which shows hemocompatible characteristic. The research has indicated that hemocompatible fixture is beneficial for proliferation a differentiation of cell, the growth of osteocytes. The earl stability is not the first concern for Biomate's osseointegration. For having a successful osseointegration, abundant blood supply is the most important think for Biomate implant. That is why we don't think that installing in the implant very tight and having the highest stability is a must for a better osseointegration on Biomate implant. We are wondering using excessive force to screw in the fixture may damage the bone and cause bone infraction due to excessive stress and lack of blood. Up to now, we can see most of Biomate's clinical cases demonstrate that Biomate implant might don't have a very high stability, but the case, especially the worse bone condition, shows that Biomate implants get a very osseointegration.



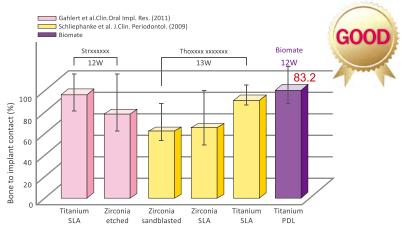


- Q8.10 Why do we say Biomate implant is suitable for immediate replacement and immediate loading?
- A8.10 After this preliminary, Prof. Dr. Amr conducted a clinical study and presented the result on June 6, 2021, "Implant Stability Changes for PDL Versus SLA Treated Surfaces in Immediate Extraction Cases: A Randomized Controlled Clinical Trial." This study finds that 1. Laser treatment of the implant surface seems to be a promising approach to promote faster bone healing, 2 PDL implant maintained higher implant stability levels in immediate implants compared to SLA, and 3. PDL implant can be a game changer in immediate extraction sockets.





- Q9.0 What is the average osseointegration period of PDL[™] treated Biomate implant? Can you provide any research for reference?
- A9.0 Generally, it requires 6 month and 3 months of osseointegration for maxillary and mandible. Biomate's implant shows similar outcome with Straumann implant at 12th week while some of the dentist applying our product install the abutment on the same day of implantation to make temporary denture for the patient. Whether or not the dentist installs the abutment immediately after implantation depends on the condition of patient, however, it is recommended to follow the general requirement stated above to increase the success rate.



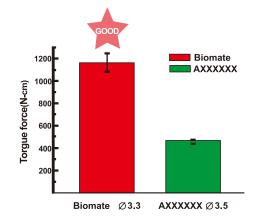
Source of Origin: Histomorphometric Analysis; by Research Center for Biomedical Devices and Prototyping Production.

- Q9.1 What is the Ra Rate of Biomate implant surface?
- A9.1 The average Ra Rate is 1.1 um.
- Q9.2 What is the size of the porous on Biomate implant surface?
- A9.2 Depth: 10-15 micron / Diameter: 10-20micron 11~12 Micro (Mainly)
- Q9.3 Have you done the pull-out test? What is the value?
- A9.3 Yes, we have done the pull-out test. Please see the following report.

Pull Out Test

The average pull-out tensile force of Biomate fixture is 1,171 Ncm, nearly 3 times larger than that of European A brand, indicating that Biomate fixture is very steady with its own design.

	Tensile force(N)										
	1	2	3	4	5	6	7	8	9	10	Avg.
Biomate	1,649	1,482	1,465	1,467	1,446	1,279	1,190	1,232	980	991	1,171
AXXXXXX	429	436	532	558	480	460	420	430	420	455	462





Q9.3 Has Biomate won any awards?

A9.3 We have won the following awards:

Biomate Implant System is of high quality equal to that of the European and American brand, and has been praised worldwide:

2011-International Warsaw Invention Show Silver Medal

2011-International Salon of Inventions and New Innovation Technologies Gold Medal

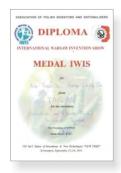
2011-European exhibition of Creativity and Innovation Special Award

2012-The 9th National Innovation Award in the Innovative Product Category

2013-16th Archimedes Moscow International Salon of Inventions and Innovation Technologies Gold Medal

According to SEM study, Biomate plus presented only few damage over the implant. The damage could be found as chipping, pit, and flattening. SLA implant presented pit, flattening, and fused surface in larger amount compare to Biomate plus. The defect could be easily found especially in apical thread corresponding to self-tapping design. Biomate plus surface did not present the sharp asperities in micro level, therefore this might be the reason why it had minimal surface alteration and more durable properties. The SLA surface generally.









I. Regarding Surface Treatment

International Quality Certifications

- Acquisition of US FDA K142174 certification for Dental Implants Systems in 2015
- Acquisition of the ISO 13485 Medical Device Quality Management System in 2012
- Acquisition of the EU/CE certification in 2012
- · Acquisition of the GMP certificate for orthodontic mini-screws and artificial scaffolds in 2012
- TFDA Registration and Market Approval of Dental Implants
- Acquisition of the US Food and Drug Administration (FDA) K103061 certification in 2011
- · Acquisition of the GMP certificate for Dental Implants Systems in 2010

International Certifications



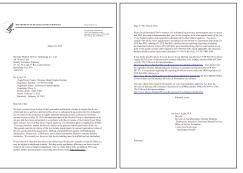












FDA Certificate



ISO 13485 Certificate



CE Certificate

Quality Assurance

Safety testing by TÜV SÜD, a certification organization that upholds the highest quality standards







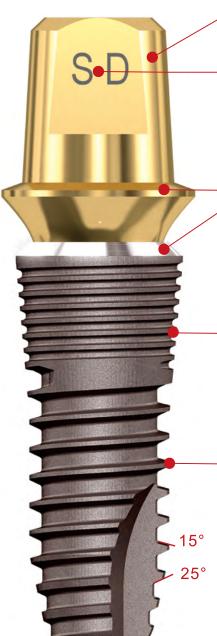


Q&A II. Regarding Fixture.

II. Regarding Fixture.

Q1.0 Biomate has two systems, Biomate and Biomate-Plus. What are the features of BIOMATE and Biomate Plus implant designs?

A1.0



Cross Section Design

 Cross section design for preventing denture rotation.



0.3mmPlatform Switch Design

- The anti-bacterial and polishing design on the platform avoid the growth of dental plaque and decrease bone absorption.
- Avoid bone loss and gum recession.



Minor External Expansion Design (Ø4.1 \ Ø4.8 \ Ø5.5)

 Increase fixture stability in primary stage and helpful for stability in extracted socket.



Root Form Design

 Tapered body for use in anatomically constricted area.



Self-Tapping Thread Design

 Ensure better primary stability and avoid excessive force causing cortical bone absorption and promotes bone tapering during insertion.

Arced Root Design

- Arc shape at the bottom of the fixture.
- Avoid damaging vital structure like inferior alveolar nerve or maxillary sinus.





Anodized Coloring Treatment Medical coloring treatment technique

- An oxide layer formed by anodic treatment color the abutment gold, increasing the aesthetic of the gum.
- Coloring treatment can improve the affinity of the abutment and gum, thus solidify the connection of fibro-tissue.



Various Abutment Specifications

- · Various abutment configurations to suit different oral conditions.
- M1.6 abutment screw is designed to be compatible to all abutments.
- Screw Driver Hex 1.25mm is designed to match all abutment configuration (Ball abutment / Positioner abutment / Multi Unit abutment excluded).



Internal Hexagon & 10° Morse Taper

Internal Hex Design

 Avoid abutment rotation, increasing stability of the connection between the fixture and the abutment.

Abutment Screw

• The abutment screw connects the abutment firmly to the fixture: such component is not subject to load, eliminating the risk of breakage.

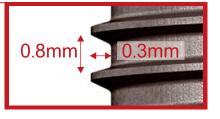


10° Morse Tapper Design

 Ensure firm connection between the fixture and the abutment. eliminating the possibility of unscrewing and micromovement, avoiding mechanical stimulation to surrounding tissue as well as preventing the intrusion of cell and bacteria.

Trapezoid Thread Design

- The lower part of the thread carries a larger angle of 25 degree allowing easier insertion of implant.
- The upper part carries a smaller angle of 15 degree preventing implant from dislodging.
- The space between the threads also forms an asymmetric trapezoid shape with a 0.3mm depth and 0.8mm apart. During the insertion of implant, the lower slope of this asymmetric trapezoid space (the upper part of the thread) squeezing the bone upward and compacting the bone into the space.
- The asymmetric trapezoid also benefits the laser processing on implant surface which providing good environment for optimal bone



0.3mm

0.7 mm



Q&AII. Regarding Fixture.

Biomate Plus Implant Design

Single pore dimension of abutment design

 With the simplification of the restoration components for Biomate & Biomate-Plus implant system. We can complete the locked function of restoration components by only using 1.25mm Hex Driver HP/RT.



Cross Section Design

 Cross section design for preventing denture rotation.



0.3mm Platform Switch Design

- The anti-bacterial and machine surface on the platform avoid the growth of dental plaque and decrease bone absorption.
- Avoid bone loss and gum recession.

0.7mm vertical machined surface

• May adjust different insertion depth according to the requirement of implant area.

0.8mm non-continuous parallel thread

• Excellent effect for maintaining the height of bone level.

Root Form Design

 Tapered body for use in anatomically constricted area.



Self-Tapping Thread Design

 Ensure better primary stability and avoid excessive force causing cortical bone absorption and promotes bone tapering during insertion.



25°

- Arc shape at the bottom of the fixture.
- Avoid damaging vital structure like inferior alveolar nerve or maxillary sinus.



Anodized Coloring Treatment

Medical coloring treatment technique

- An oxide layer formed by anodic treatment color the abutment gold, increasing the aesthetic of the gum.
- Coloring treatment can improve the affinity of the abutment and gum, thus solidify the connection of fibro-tissue.



Various Abutment Specifications

- · Various abutment configurations to suit different oral conditions.
- M1.6 abutment screw is designed to be compatible to all abutments.
- Screw Driver Hex 1.25mm is designed to match all abutment configuration (Ball abutment / Positioner abutment / Multi Unit abutment excluded).



Internal Hexagon & 10° Morse Taper

Internal Hex Design

 Avoid abutment rotation, increasing stability of the connection between the fixture and the abutment.

Abutment Screw

· The abutment screw connects the abutment firmly to the fixture: such component is not subject to load, eliminating the risk of breakage.

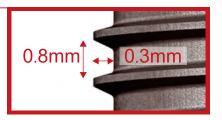


10° Morse Tapper Design

• Ensure firm connection between the fixture and the abutment. eliminating the possibility of unscrewing and micromovement, avoiding mechanical stimulation to surrounding tissue as well as preventing the intrusion of cell and bacteria.

Trapezoid Thread Design

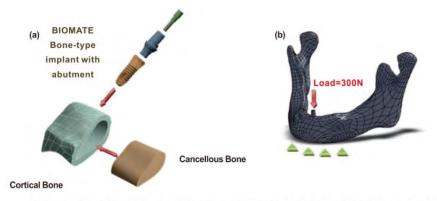
- The lower part of the thread carries a larger angle of 25 degree allowing easier insertion of implant.
- The upper part carries a smaller angle of 15 degree preventing implant from dislodging.
- The space between the threads also forms an asymmetric trapezoid shape with a 0.3mm depth and 0.8mm apart. During the insertion of implant, the lower slope of this asymmetric trapezoid space (the upper part of the thread) squeezing the bone upward and compacting the bone into the space.
- The asymmetric trapezoid also benefits the laser processing on implant surface which providing good environment for optimal bone



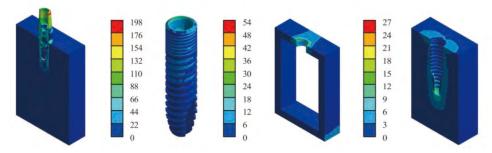


Q&AII. Regarding Fixture.

- Q2.0 Why is there external expansion on Biomate Implant? What is the theory? What is the advantage?
- A2.0 During research and design process, we discovered that the external expansion can effectively disperse the occlusal force. Please refer to the picture of FEA on our catalogue.



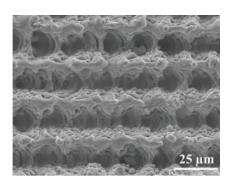
The result of simulation shows that the force is evenly dispersed to the surface instead of a single point.



- Q3.0 Why is the bottom of Biomate and Biomate Plus implant arced? What is your theory? What is the benefit of such design? Why isn't it sharp?
- A3.0 Biomate Implant is designed with an arced bottom and asymmetrical trapezoidal thread; you can see that it has no sharp edge at all compare to most brands in the market, mainly design to avoid any stimulation or harm to the patient's bone and nerves during surgery.
- Q4.0 What is your system advantage?
- A4.0 **1. A unique implant with the laser surface treatment and asymmetric trapezoid thread** 1-1 **PDL laser** treatment makes a unique structure which possesses two unique characters: (A). A high oxidized surface which achieved high hemocompatibility offering an environment for fibrin attach then benefit for provisional matrix forming that is important for the early stage. (B). Microchannel with micro-nano complex 3D pore. The microchannel induced the precursor of osteoblast directional moving onto the implant surface faster than any other implant with different surface treatment, Finally, the micro-nano 3D pore improving the efficiency of osteoblast adherence, proliferation, differentiation, and finally,bone formation.



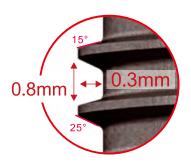
Q&AII. Regarding Fixture.



1-2 Asymmetric trapezoid Thread Design can afford the high laser energy and also carry the following advantages.

The lower part of thread carries a larger angle of 25 degree allowing easier insertion of implant The upper part carries a smaller angle of 15 degree preventing implant from dislodging. The space between the threads also forms an asymmetric trapezoid shape with a 0.3mm depth and 0.8mm apart. During the insertion of implant, the lower slope of this asymmetric trapezoid space (the upper part of the thread) squeezing the bone upward and compacting the bone into the space.

The asymmetric trapezoid also benefits the laser processing on implant surface which providing good environment for optimal bone contact.



2. A complete Prosthetic Parts.

This system contains all kinds of abutments, one piece abutment, two piece Abutment, Angel Abutment, UCLA Abutment, Shaping Abutment, Temporary Abutment, Ball Abutment, Multi-Unit Abutment and Positioner (Locator) and CAD/CAM Abutment. The system can help doctors to make the best functional and beautiful prosthetics.







₩ II. Regarding Fixture.

3. CAD/CAM system

Biomate has CAD/CAM system to provide customized abutment and denture for dentists to deal with the issue of abutment angle.



4. Digital Implant System

Offer Digital Implant software to help doctors to do the guided surgery.

			J ,
	Dentist End		Biomate Lab / Local Lab
Step I	-CT scanning -Plaster modeling -Oral Scanning (optional)	Step II	-Scan oral model -Build 3D simulation
Step III	Write implant plan	Step IV	Based on doctor's implant plan,Biomate dentist group (local lab)designs surgery plan
Step V	Confirm surgical plan (which is designed by Biomate Lab /Local Lab)	Step VI	Manufacture and deliver 3D guide templates
Step VII	Sterilize surgical tools(Bionavi) Implant Surgery		

5. Easy Use Surgical Kit

A simple design with clear color-coding Simple and easy surgical procedure A mount-free design

- Q5.0 Biomate Implant is similar to ASTRA Implant. ASTRA presented their product on a journal that no interstices exist between the connection interface between the external expansion and cortical bone. Does Biomate Implant show the same outcome?
- A5.0 Yes. The internal bore taper angle of Biomate Implant corresponds to the angle of connection interface of the abutment, which belongs to stationary fit or transition fit in mechanical design theory. The tolerance of the fitting between the implant bore and the abutment is very small, thus it shows similar result to that of the Astra Implant.

For comparing the strength, We have taken a pull test to see the difference between Ankylos implant and Biomate implant. The pull-out test results are summarized in Table as below. Obviously, the average pull-out force of Biomate and Ankylos implants were 1171 N-cm and 462 N-cm respectively.



	Force (N-cm)										
	1	2	3	4	5	6	7	8	9	10	Avg.
Biomate	1649	1482	1465	1467	1446	1279	1190	1232	980	991	1171
Ankylos	429	436	532	558	480	460	420	430	420	455	462

Q6.0 What differences between Biomate and Biomate Plus A6.0

System	Biomate Implant System		Biomate Plus Implant System					
Size	S	D	R	.D		S	D	
Diameter	3.3	4.1	4.8	5.5	3.5	4.0	4	.5
Length	8/10/12/14	8/10/12/14	8/10/12/14	8/10/12/14	8/10/12/14	8/10/12/14	8/10/12/14	8/10/12/14
Characteristic	1. Minor External Expansion Design (D4.1, D4.8, D5.5) 2. Root Form Design 3. Arced Root Design 4. 03mm/0.4 mm Platform Switch Design 5. Trapezoid Thread Design 6. Self-Taping Thread Design PDL (Precision Dimension Laser) surface treatment create micro channel and 3D			1. Single Pore Dimension of Abutment Design (SD) 2. 0.3mm Platform Switch Design 3. 0.7mm vertical smooth surface 4. 0.8mm non-continuous parallel thread 5. Root Form Design 6. Arced Root Design PDL (Precision Dimension Laser) surface treatment create micro channel and 3D				
	Pore, which lead the bone cell directionally move to the surface of implant. The 3D provides the best environment for attachment and the growth of osteocytes.			Pore, which lead the bone cell directionally move to the surface of implant. The 3D provides the best environment for attachment and the growth of osteocytes.				
Clinical Applicability	 The early stability is crucial need. D3, D4 Bone (Bone condition is very worse) Sinus Lift The senior patient Immediately loading 		1. D1 to D3 Bone 2. Regular and healthy Bone 3. for minimally invasive surgery					

- Q7.0 Biomate's implant body length and diameter is a little bit different from "BioHorizons" and "Implant Direct" implants. So, I need to know why did you choose these length and diameters in specific?
- A7.0 Biomate implant system was developed on 2008. At that time, the manufacturing technology is not mature for the small diameter. Most of implant is from 3.5mm. Through the surveying, the Asian people have the smaller mouth jaw comparing to that of the Western people. Therefore, we select sizes for the smaller jaw, from 3.3mm (especially for Anterior Aesthetic Zone), 4.1mm, 4.8mm and 5.5mm. length: 8mm, 10mm, 12mm, 14mm.)





Q&A II. Regarding Fixture.

- Q8.0 Doctors want to know that why the samllest Biomate implant fixture is 3.3, which do not diverge as the other brand size as 3.5.
- A8.0 Because it is for anterior aesthetic area, we need small size to provide more room for buccal bundle bone.
- Q9.0 Are you planning to produce implant with length >14 mm?
- A9.0 Our current implants lengths are designed in 8, 10, 12, 14 (mm) according to the normal human anatomy structure. We do not plan to develop the longer implants than 14mm. The reasons are as below:
 - 1. In maxilla, when doing the sinus lift, the longer implant might have higher risk of hurting the Schneiderian membrane.
 - 2. In mandible, the longer implant might hurt the inferior alveolar nerve.
 - However, please let me know if your market needs the longer implants and let me know the reasons why your doctors need it. And then, I will discuss with R&D to see the possibility of development.

	Dimensi	on Table		Unit : mm	
Fixture	SD-Small		RD-Regular		
Diameter	3.3	4.1	4.8	5.5	
Length	8 10 12 14		8 10 12 14		

	Dimension Ta	ble	Unit : mm
Fixture	SD-Small	SD-Small	SD-Small
Diameter	3.5	4.0	4.5
Length	8 10 12 14	8 10 12 14	8 10 12 14



Q&A

III. Regarding Abutment and Screw

III. Regarding Abutment and Screw

Q1.0 What is the features of Biomate abutment?

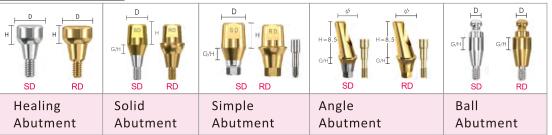
A1.0

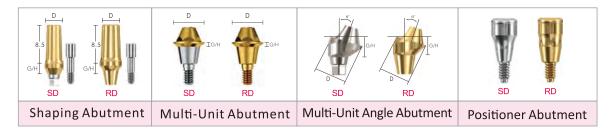
1. The Biomate abutment product line are composed of 4 types of diameter, 3 types of denture installation height, and 4 types of gum height, with a total of 250 types of abutments for use.

Simple Abutment (Hex / Non-Hex)	SD-Small			RD-Re	В В В В В В В В В В В В В В В В В В В	
Diameter	4.0	4.5	5.0	5.0	6.0	
	4.0			4.0		
Height	5.5			5.5		
	7.0			7.0		
	1			1		
Gingival Height	2			2		
	3			3		
		4		4		

2. In order to recognize the difference of SD and RD, Healing, solid, simple, angle, and shaping abutment has been made, SD as silver and RD as golden.

SD-RD Abutment



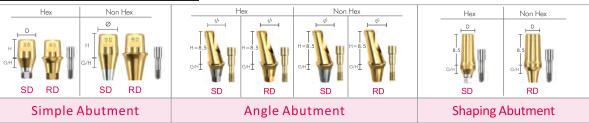




Q&A III. Regarding Abutment and Screw

3.In order to have more option for the clinical need, Simple, Angle, Shaping, Temporary, UCLA and Multi-Unit abutment have hex and non- hex design.

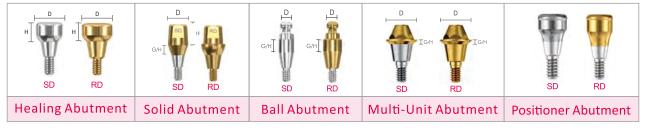
Hex and Non Hex Abutment





4. The healing, Ball Abutment and Solid Abutment is one piece design without the central screw.

One-Piece Abutment



- Q2.0 Biomate's Ball Abutment and positioner are designed for the removeable denture. Please explain what is the difference between Ball Abutment and positioner?
- A2.0
 The divergence of ball abutment is between 10 degree and 15 degree
 The divergence of positioner is between 10 degree and 20 degree.
- Q3.0 Please explain the difference among Shaping, Simple and CAD/CAM Abutment
- A3.0 We can simply say the Simple Abutment is uniform Abutment, shaping is half-tailor Abutment and CAN/CAM is tailor Abutment.

Simple Abutment's diameter, height, and gingiva height are fixed. (diameter, 4.0,4.5, 5.0 and 6.0 / height, 4.0, 5.5 and 7.0 /Gingival Height, 1.0, 2.0, 3.0, and 4.0)Shaping Abutment's height is 11.

So, when a dentist needs height is above 7.0, he can chose Shaping Abutment to shape the height as he need.

CAD/CAM Abutment is a abutment made as totally as dentist's need.



III. Regarding Abutment and Screw

- Q4.0 How long is the abutment screw of Biomate Implant System?
- A4.0 The length of abutment screw is 8.5mm, with effective thread length of 2.65mm, width 1.6mm, pitch 0.35mm and possesses 7 threads. We believe the proper length and width are the key for assembling the implant and the abutment. Through our studies, to avoid the distortion, we designed the 1.6mm, instead of 1.4mm for the other brand, as our abutment screw. And it shows much better fatigue resistance than other brands.
- Q5.0 What is the maximum static force Biomate implant can bear?
- A5.0 The assembled implant and abutment, according to mechanical property test, can bear the power of 1000N (around 100 kg) before its destruction.
- Q6.0 What is the size of the screw?
- A6.0 All four diameters of Biomate implant use the same M1.6 screw, which has undergone the test of ISO 14801 fatigue test that can bear human lateral occlusal force over 5 million times.
- Q7.0 How will non hex Ball Abutment and Solid Abutment fit with hex fixture?
- A7.0 A: Non hex Ball Abutment and Solid Abutment fit with hex fixture by thread.

Product name		Picture	Interpretation
Solid Abutment	Thread		
Ball Abutment	Thread	Thread	No hex Ball Abutment and Solid Abutment fix with fixture by thread.

Q8.0 May you explain the differences between (hex and non-hex) in Simple Abutment, 15° Angled Abutment, 25° Angled Abutment, Shaping Abutment, Temporary Abutment, and UCLA Abutment

A8.0

Internal connection	Hex	Non Hex			
Picture					
Interpretation	Non-Hex abutments are used when prosthetic units are splinted together(ex.bridge or bar). The main reason is because of placement difficulties(due to line of insertion), if a hex is used (and of course rotation is not an issue because of multiple units being joined). Hex abutments are used as an anti-rotational mechanism for any abutment that might rorate(ex.signle unit crowns)However, usually Ball abutment and Positioner Abutment do not use a hex because of the direction of screwed directly into the implant and usually do not come loose.				
material	From Dale Gerke-BDS, BScDENT				



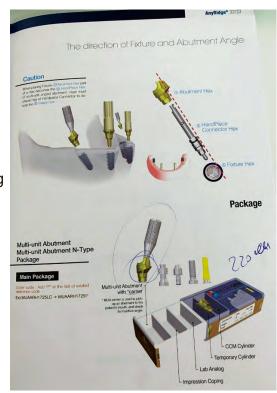
III. Regarding Abutment and Screw

Q9.0 How to read the dimension of abutment. A9.0

				-	
Item Number	Product Name	Dimension	Photo	Interpretation	Remarks
1AA-315	Healing Abutment(mark)	D4.0 H7.0 G3 (MARK)-SD	Y	Diameter 4.0mm/ Height 7.0mm/ Gingival height 3mm/Mark	
1AA-316	Healing Abutmen(mark)	Healing Abutmen\ 4.0 × 2.0(G1)		Diameter 4.0mm/ Height 2.0mm/ Gingival height 1mm/Mark	
4AA-A45	Solid Abutment	Solid Abutment \ 4.0 × 5.5 × 2(s)	RD	Diameter 4.0mm/ Height 5.5mm/ Gingival height2mm /Small Diameter	The first number of dimensions is diameter. the second one is height. the third one means gingival height.
4AA-D02	15°Angled Abutment	15°Angled Abutment \ 4.0 × 8.5 × 4(s)		Diameter 4.0mm/ Height 8.5mm/ Gingival height 4mm/Small Diameter	33 3
4AA-H45	Shaping Abutmen	5.0×11 G/H1.5		Diameter 5.0mm/ Height 11mm/ Gingival height 1.5mm	

Q 10. Please see attached the Multi-Unit offer from Megagen in Romania. As you can see they have a full package that includes the abutment (doesn't matter if it is straight or angled), CCM Cylinder, Temporary Cylinder, Impression Coping and Analog. Do you have this package? Do those components come with conection abutments or the abutments are being sold separately.

A 10. I am sorry that we don't have the same package as Megagen's Multi Unit Abutment N Type package. You need to buy these items separately. Refer to Megagen's package, you can pack Biomate's Multi Unit Abutment Holder, Multi Unit Metal Cylinder (same as Megagen's CCM Cylinder), Multi-Unit Titanium Cylinder (same as Megagen's Temporary Cylinder), Multi-Unit Impression Copying Transfer, and Multi-Unit Analog together as a package to sell to your local users who like to have the same package as Megagen.





- Q 11. What is the difference between metal cylinder and titanium cylinder?
- A 11. The difference between Metal Cylinder and Titanium Cylinder is: Metal Cylinder is the combination of plastic and metal, Titanium is whole titanium designed.

 The manufacturing cost is in Metal cylinder is higher than Titanium Cylinder.
- Q 12. Please confirm that the premill abutment, ti base and scan body come with the connection screw and how many.
- A 12. We confirm all of Premill abutment, ti base and scan body come with the connection screw. Premill Abutment is packed with 2 screws, Ti-Based Abutment is packed with 2 screws, and Scan Body is packed with 1 screw.
- Q13. What about the Angled Multi-unit abutment Screw? Does it come with the Angled Multi-Unit abutment?
- A 13. Every one of angle muti-unit abutment is packed with Angled Multi-Unit abutment screw ..
- Q14. Does Positioner abutment is compatible with Zest?
- A 14. Please kindly be noted that the whole Positioner system (including driver and tools) is compatible with Zest.
- Q15. Please let me know your opinion and send me a picture of an actually manufactured premill abutment. Because They should have the hex connection created and from the picture, I have that can't be seen.
- A 15. Please refer to the attached picture, from this picture, you will see it has hex connection.



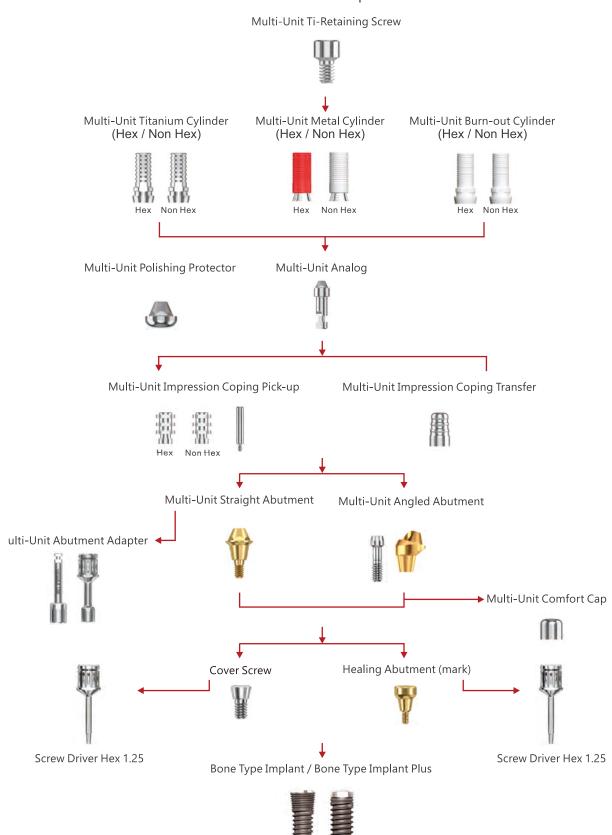




Q16. What is your flowchart of Multi-Unit Abutment A 16.

Multi-Unit Straight / Multi-Unit Angled

Abutment Level Impression



III. Regarding Abutment and Screw

- Q17. I don't understand what is the height of membrane screw.
- A17. Attached technical Scheme for your understanding.

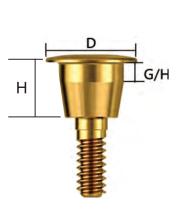


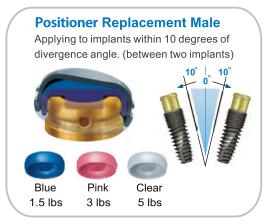
Image	Description	Catalog No.	Dimension	Socket
	Membrane Screw	1AA-111	D3.3H5.5G0	SD
	Membrane Screw	1AA-112	D3.3H6.0G0.5	SD
	Membrane Screw	1AA-113	D3.3H6.5G1	SD
	Membrane Screw	1AA-114	D3.3H7.5G2	SD
	Membrane Screw	1AA-115	D5.0H5.5G0	SD
	Membrane Screw	1AA-116	D5.0H6.0G0.5	SD
	Membrane Screw	1AA-117	D5.0H6.5G1	SD
T T	Membrane Screw	1AA-118	D5.0H7.5G2	SD
# #	Membrane Screw	1AA-103	D4.8H6.2G0	RD
	Membrane Screw	1AA-104	D4.8H6.7G0.5	RD
	Membrane Screw	1AA-105	D4.8H7.2G1	RD
	Membrane Screw	1AA-106	D4.8H8.2G2	RD
	Membrane Screw	1AA-107	D6.0H6.2G0	RD
	Membrane Screw	1AA-108	D6.0H6.7G0.5	RD
	Membrane Screw	1AA-109	D6.0H7.2G1	RD
	Membrane Screw	1AA-110	D6.0H8.2G1.5	RD

- Q18. Please let me know What other drivers are needed for the positioner abutment and IF they are fully compatible with the Zest System.
- A18. Biomate Positioners system is fully compatible with the Zest System. We offer the following two items for doctors to use Positioners.

Positioner Torque Driver S	Positioner Torque Driver L	Positioner Core Tool
		⊗ BIOMATE

Q19. Would you tell me the differences between the replacing male in each color please?





Positioner males are dental consumables. For Positioner male, the higher the retention, the tighter the replacing male attach to the positioner abutment. In most cases, treatments start with lighter retention replacing males. After a while, due to the chewing, replacing males start to loosen up. Therefore, dentists will treat their patients with higher retention replacing males.



IV. Regarding Thread and Internal Connection

- Q1.0 Please advise the design theory of the pitch and depth of the implant thread.
- A1.0 Documents below show why pitch 0.8 is a better design:
 - 1.Taiwan thesis: Effect of different thread geometry and inter-distances on the osseointegration of dental implant with Lan-Yu mini-pig model http://cetd.tmu.edu.tw/etdservice/detail?n=1&list=1%A1B&etdun1=U0007-3006201111293100&& query_field1=keyword&query_word1=bone-to-implant%20contact&start=1&end=1
 - 2.International periodical: Optimized thread pitch design and stress analysis of the cylinder screwed dental implant http://www.ncbi.nlm.nih.gov/pubmed/17334071

 Both documents concluded that pitch 0.8 is a better design.
- Q2.0 Please explain the reserved space at the bottom of the internal bore.
- A2.0 The reserved space under the thread and hexagon of the bottom of the internal bore is designed for processing allowance. The relation between the screw and thread, regarding the data from both the other brands and our own, 4~5 joint of threads shall be enough. Some implant systems provide implant with closer bolt thread and nut thread for shorter implant (lesser thread number means shallower bore). Such design concerns mainly processing type and has less influence on the clinical effect of the joint between the implant and the abutment after long-term implantation.



The reserved space at the bottom of the internal bore.



- Q3.0 What are the differences between the internal hexagon, internal octagon and internal bi-hexagon connections?
- A3.0 The difference between the internal hexagon, internal octagon and internal bi-hexagon connections are the angles for placing in the abutments. Each angle of the internal hexagon is 60 degree, internal octagons have angles of 45 degree, and internal bi-hexagon angles are 30 degree. The more angles the socket has, the easier dentist can place the abutment in correctly. Internal hexagon connections have the strongest endurance that is least likely to be damaged. Though it is harder to aim the angles on the abutment correctly to the angles of the internal hexagon in the fixture, using the marks designed on the Implant Driver can help dentists clearly identify and place the abutment correctly without concerns for damaging the internal hex when installing fixtures.

Contrarily, although it is easier to match the angles for internal bi-hexagon, it is also more likely to be damaged. If fixtures with internal bi-hexagon connections are placed in bones with higher bone density and locked too tightly, it may damage the internal socket, and the implantation would be unsuccessful.

- Q4.0 What is the reason for replacing external hexagon type with internal hexagon socket type?
- A4.0 The stress structure of external hexagon is less efficient compared to internal hexagon sockets, thus the abutment screw has a higher possibility of breaking. Moreover, the adjoining plane of external hexagon is exposed to soft tissues allowing bacteria to accumulate in the gaps. These gaps fluctuate when pressure is put on the abutment, creating a pumping effect that will absorb more bacteria. This will cause a higher failure rate for implantation. Therefore, the internal socket connection design was developed, facilitating better endurance, solving the problem of bacteria accumulation, and increasing the success rate of dental implantation.





IV. Regarding Thread and Internal Connection

- Q6.0 Would you tell me the differences of your thread design?
- A6.0 Biomate's thread design has the following differences you need to understand and please be remembered.
 - Asymmetric trapezoid Thread Design can afford the high laser energy and also carry the following advantages.
 - The lower part of thread carries a larger angle of 25 degree allowing easier insertion of implant
 - The upper part carries a smaller angle of 15 degree preventing implant from dislodging.
 - The space between the threads also forms an asymmetric trapezoid shape with a 0.3mm depth and 0.8mm apart. During the insertion of implant, the lower slope of this asymmetric trapezoid space (the upper part of the thread) squeezing the bone upward and compacting the bone into the space.
 - ■The asymmetric trapezoid also benefits the laser processing on implant surface which providing good environment for optimal bone contact.
 - 2. Due to the high energy of laser, Biomate implant has trapezoid thread design. This design can afford the high energy of laser bean, but also the asymmetric trapezoid space (the upper part of the thread) squeezing the bone upward and compacting the bone into the space. However, the trapezoid thread is not so sharp as the most of other threads, such as triangular thread and serrated thread.



Drawing		<i>A</i>	J.	<i></i>
Category	Rectangular thread	Triangular thread	Trapezoidal thread	Serrated thread
Image				Spark

3. Biomate's laser treated surface is provided 3D pores and micro channel with hemocompatible characteristic, which is beneficial for water soluble proteins adherence, osteocytes proliferation and differentiation. For this structure, besides the primary stability, blood supply is the key factor for bone healing process. The too high stress during insertion might jeopardize the blood circulation around implant. If the fixture can't not be fully screwed in, please unscrew the fixture and verify the diameter of the hole. Or please use tap to form the thread. Please never force the fixture to screw into the bone. Using excessive force to screw in the fixture may damage the microchannel structure and decrease the blood supply in the surrounding. It is recommended to unscrew the fixture and re-tap the hole with our dedicated tap to form the thread.

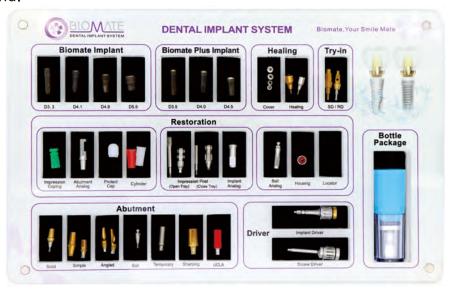




V. Regarding Accessory of Prosthetics

V. Regarding Accessory of Prosthetics

- Q1.0 Is it possible to perform direct impression on Biomate abutment?
- A1.0 Yes, direct impression is applicable on the abutment, however, it is still recommended to use Biomate prosthetic components to can decrease surgical time with better precision.
- Q2.0 How many types of impression coping do you have?
- A2.0 There are three types of impression coping: quick impression, open-tray impression and close tray impression; the dentist can choose upon their own demand.



- Q3.0 What are the differences between a cylinder single and a cylinder bridge?
- A3.0 Cylinder single and cylinder bridge are for Dental Laboratory to use.

Cylinder Single	Cylinder Bridge
For making single crown only	For making overdentures

- Q 4.0 What is the difference between Impression post open tray and Impression post close tray
- A 4.0 Please find attached video regarding to the differences between impression post-open tray and close tray.



Open Tray: https://www.youtube.com/watch?v=htV86HWqXGQ Close Tray: https://www.youtube.com/watch?v=gSZHIKq4FxE



- Q5.0 Open and Close tray, which one is used more often?
- A5.0 a. Regarding to impression post-open tray and close tray: Since the operation procedure of close tray is more convenient, it is more commonly sold than open tray.
 - b. For Cylinder single and Cylinder bridge, few people would use the two items.
- Q6.0 Why there are both implant and abutment analogue and in which cases each one can be used?

A6.0

Abutment Analogue	Implant Analogue
Use for laboratory fabricated abutment level cast models	Use for a laboratory fabricated implant level cast model

- Q 7.0 How to tell the difference between SD / RD?
- A 7.0 1. Implant:

SD- Biomate series 3.3/4.1, Biomate Plus series 3.5/4.0/4.5 RD- Biomate series 4.8/5.5

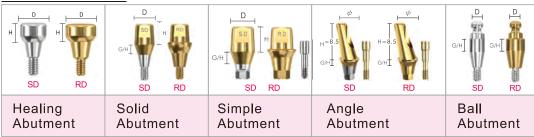
2. Healing abutment:

SD - silver RD - gold

3. Simple abutment:

SD - two colors of silver and gold RD - gold

SD-RD Abutment





- Q 8.0 Mult Unit Analog (are these reusables?)
- A 8.0 Yes, it is reusable.
- Q 9.0 Is Multi-Unit abutment holder reusable?
- A 9.0 Every multi-unit abutment is packed with holder. So, it is no need to reuse.

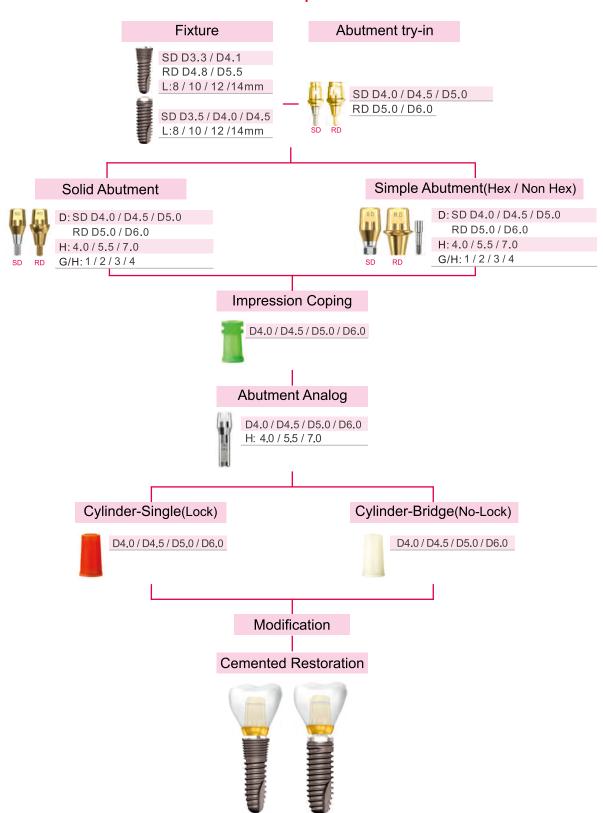




- Q 10.0 The flow chart of the impression coping
- A 10.0 There are prosthetic components for three ways of impression coping.

 1. Quick Impression 2. Open tray and 3. Close tray.

Quick Impression

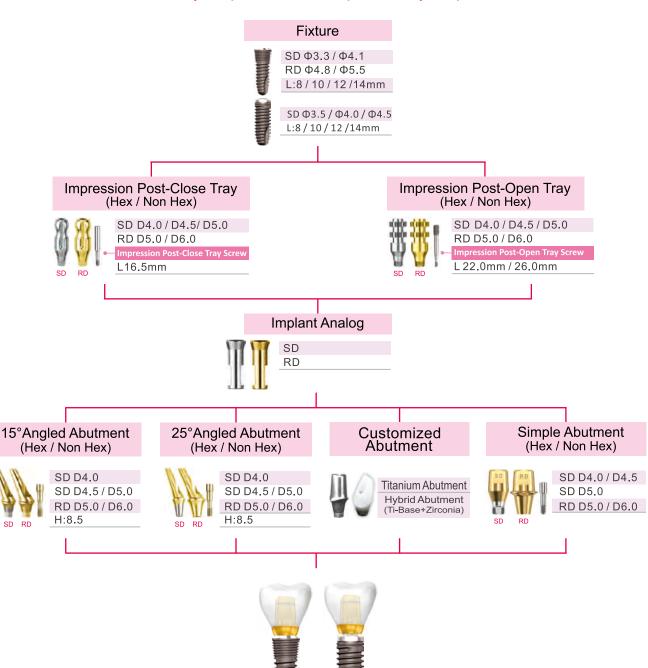






V. Regarding Accessory of Prosthetics

Close-Tray Impression & Open-Tray Impression





VI. Regarding the Material

- Q1.0 What is the material of Biomate implant?
- A1.0 Biomate applies the Medical Grade IV Pure Titanium (99% Pure Titanium) imported from Carpenter Company of the US, which is of the same level of European and US brands.
- Q2.0 What is the difference between Grade V and Grade IV pure titanium?
- A2.0 Pure titanium scale from Grade I to IV contains 99% pure titanium, while Grade V belongs to a kind of titanium alloy composed of 6% aluminum, 4% vanadium and 90% titanium, which has higher strength but lower plasticity; therefore, Biomate applies Medical Grade IV Pure Titanium that possess higher solidity and plasticity.
- Q3.0 What is the material of screw?
- A3.0 Titanium Grade V.
- Q4.0 What is the benefit of pure titanium grade IV over other grades?
- A4.0 Grade IV titanium it contains 99% pure titanium which has higher biocompatibility than Grade V titanium alloy.
- Q5.0 What is the material for quick impression? How many times can it be used?
- A5.0 The parts use in quick impression are made of plastic; it is recommended to use only once, however, the dentist can decide the actual usage.
- Q6.0 What is the material for close-tray and open-tray impression? Can it be used repeatedly?
- A6.0 The parts use in close-tray and open-tray impression are made of grade IV titanium (Ti6AI4V);it is recommended to use only once, however, most dentists will decide upon their own demand.



VII. Regarding Tests

- Q1.0 On what projects do you apply sampling test?
- A1.0 We apply MIL-STD-105E of US Arm Force sampling standard on some of our QA processing.
- Q2.0 What is the defect rate of your product?
- A2.0 Our target defect rate is set under 2%, and all defect products will be handled with ISO 13485 to perform strict procedure control, but the defect rate of our final product is certainly 0%.
- Q3.0 The fatigue test is one of the key points of implant product. One major problem of dental implant is the fracture of abutment and abutment screw, which is really troublesome. The abutment screw of Biomate Implant System is really long; can you please advise its length? Can you provide the data of fatigue test for reference?
- A3.0 The size of the screw is not the definite key to the design of our product, but whether or not the stress is relieved at the turning point. Only by relieving of stress will it not focus on the sharp edge thus the strength increases. Such design can effectively increase the mechanical strength comparing to the screw of the same size. The regulation of fatigue test does not regulate the maximum of time the test item shall undergo but a minimum of 5 million times is required. Generally, we set an occlusal force of 120N(around 12kg) and hit the test item 5 million times; unless the patient has excessive occlusal force, normal bearing shall not cause fracture to the abutment screw. Test item undergo the test with above stated condition without fracture have passed fatigue test, destruction due to fatigue shall not occur under such force.
- Q4.0 How many kilograms do you apply for fatigue test?
- A4.0 We've set a minimum of 120N(about 12kg), and hit the test item 5 million times. Most implant manufacturers apply 30N(around 3kg); Biomate applies 120N on the test item, which is 4 times heavier than that of the other brands. Our product can bear occlusal force up to 120Ncm (around 40kg), which is unreachable to most people, therefore, it is almost impossible for our implant, Abutment or Abutment screw to break (we've perform test on all three at the same time). Dentist can be confident in using our product.
- Q5.0 Regarding your screw, do you have tested it and is it easy to broken?
- A5.0 We have made some tests at the Technic University in Timisoara, Romania. And the screw is broken at 45Ncm. We have used about 12 abutments for these tests because we have also tested the vertical impact resistance and other things.

VIII. Regarding Surgical Instrument

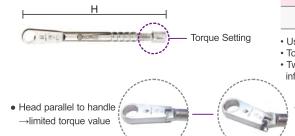
Q1.0 What is the feature of your surgical kit?

A1.0

- 1. The most special part of our surgical drill is that we designed a drill that is suitable for both D3.3 and D4.1 implant, which can decrease the time of surgery.
- 2. Biomate's cover screw and healing abutment share the same bore with the same D1.25 screw driver.
- 3. The D1.25 screw driver coordinates with international standard that can be applied to most famous brands.
- 4. Color distinguish management is applied on all implants and surgical kit, making the surgery smoother and faster.
- 5. Wrench can adjust torque.

Torque Ratchet

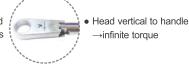
Unit: mm



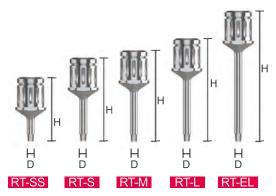
Name	Torque	Height (H)	Catalog No.
Torque Ratchet	10~40Ncm	83	3AA-034

- · Used in combination with the implant driver or the screw driver
- Torque can be set from 10 40 Ncm or to infinite
- Twist the adjustable end to set the required torque value; loosen fully to achieve infinite torque

Bent ratchet head indicates torque is at its limit



6. Two stage surgical instrument uses same size screw drill.



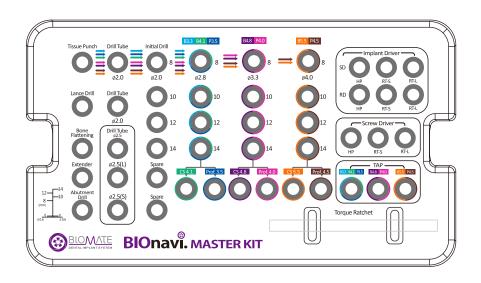
品 名	尺寸規格(D)	長度(H)	型號		
	Hex 1.25-HP-S	19	3AA-033		
	Hex 1.25-HP-L	25	3AA-041		
	Hex 1.25-HP-EL	31	3AA-145		
Screw Driver	Hex 1.25-RT-SS	14.8	3AA-146		
(HP/RT)	Hex 1.25-RT-S	19.8	3AA-042		
	Hex 1.25-RT-M	21.8	3AA-147		
	Hex 1.25-RT-L	24.8	3AA-043		
	Hex 1.25-RT-EL	31.8	3AA-148		
※用於收輸合配件(Cover Screw/Healing Abutment)或應復配件					

- ※用於將癒合配件(Cover Screw/Healing Abutment)或贋復配件 (Abutment)與植體結合
- ※HP需搭配植牙機,RT需搭配扭力板手
- 7. 3.3 and 4.1 sizes use same Final Drill
 - (3.3 size is straight and 4.1 size is extended, so using the same drill can save the cost and time of using two different drills)





Q2.0 Do you have surgical kit for guided surgery and how to use it? A2.0 Yes, we offer Bionavi for the guided surgery.

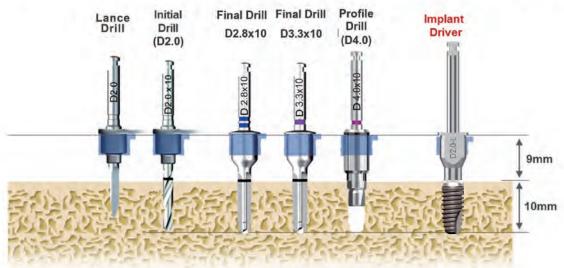


Bionavi. Surgical Instruments

Drilling Sequence of Instruments:

1.Recommended speed setting: 50RPM/40N (No feed water)

2.For high bone density(D1/D2),recommended speed setting of Guide Drill & Initial Drill is 800RPM/20N (feed water)

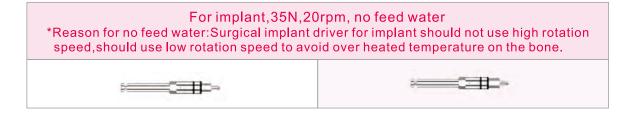




Bone Density: D2 Bone, Biomate Plus, Ø4.0 x10 mm Placement

- Q2.0 What is the diameter of the hexagon screw driver?
- A2.0 The size of the hexagon screw driver is 1.25mm, which can be applied on all our second- stage products including cover screw, healing abutment, prosthetic abutments as well as prosthetic components.
- Q3.0 What is the recommended turning speed/torque for drilling and implant placement on the motor and torque ratchet? Should there be feeding water?
- A3.0 The recommended speed of drilling is 1200rpm/20N torque with feeding water; 20rpm/35N torque without feeding water for implantation.





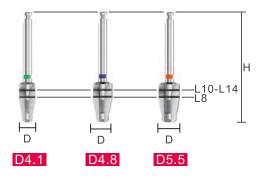


- Q4.0 What is the recommended torque for the installation of cover screw, healing abutment or prosthetic abutment? What is the standard value?
- A4.0 It is recommended to screw in the abutment screw and healing abutment manually, the torsion used should be determined by the stability of the fixture in the patient. However, it is recommended to use 30N for screwing in prosthetic abutments.



- Q5.0 Biomate Implant is similar to Astra implant; are the surgical instruments compatible? or are they compatible to other brands?
- A5.0 Round bur, Lindemann drill, lance drill, drill extender and adapter in Biomate surgical kit are compatible to all implant system while round torque ratchet, screw driver, initial drill, guide pin and paralleling pin are compatible to certain implant systems.
- Q6.0 Is it possible to collect bone at lower speed?
- A6.0 Yes, but it is still recommended to use 1200rpm turning speed, 20N torque with feeding water when drilling.
- Q7.0 Is Biomate drill using inner flush or outer flush?
- A7.0 We use outer flush. It is because inner flush would not clean thoroughly and sometime may cause rust problem. Please use saline solution on both up and down drilling in order to avoid bone from over-heated.
- Q8.0 What is the rotation speed for Biomate drill?
- A8.0 The rotation speed for Biomate drill would be at 800~1200 rpm.
- Q9.0 How to use countersink?
- A9.0 Used to trim the cortical bone will rotation speed 1,200rpm, torque 20Ncm, feed water; each drill corresponds to different diameters of fixtures. Countersink should be used for bone D1-3, but bone D4 can be skipped with this step.

Counter Sink Unit : mm



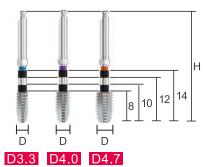
Name	Diameter (D)	Height (H)	Catalog No.	Fixture Ø
	D4.1	29	3AA-014	4.1
Counter Sink	D4.8	29	3AA-015	4.8
	D5.5	29	3AA-016	5.5

- Used to trim the cortical bone with rotation speed 1,200rpm, torque 20Ncm, feed water; each drill corresponds to different diameters of fixtures
- Drill to the second laser mark for L10-L14 Implant or the first for L8mm Implant
- Counter Sink Ø4.1 is used after Final Drill Ø2.8
- Counter Sink Ø4.8 is used after Final Drill Ø3.3
- Counter Sink Ø5.5 is used after Final Drill Ø4.0

Q 10.0 What is the product instruction of using tap?

A 10.0 Use on D1 bone to create threads inside the hole; each drill corresponds to different diameters of fixture. Used with rotation speed set at 20rpm, torque 35Ncm; set the implant motors to reversed rotation to withdraw the instrument after drilling.

Tap Unit: mm



Name	Diameter (D)	Height (H)	Catalog No.	Fixture Ø
	D3.3	29	3AA-017	3.5
Тар	D4.0	29	3AA-018	4.0
	D4.7	29	3AA-019	4.5

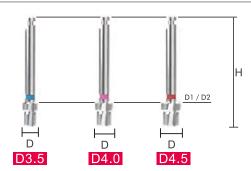
- Used on D1 bone to create threads inside the hole; each drill corresponds to different diameters of fixtures
- Used with rotation speed set at 20 rpm, torque 35 Ncm; set the implant motors to reversed rotation to withdraw the instrument after drilling
- Tap Ø3.3 is used after drilling with Final Drill Ø2.8 and Counter Sink Ø4.1
- Tap Ø4.0 is used after drilling with Final Drill Ø3.3/ Counter Sink Ø4.8
- Tap Ø4.7 is used after drilling with Final Drill Ø4.0/ Counter Sink Ø5.5

VIII. Regarding Surgical Instrument

Q 11.0 What is the product instruction of using profile

A 11.0 Use profile drill for trimming the cortical bone according to patient's bone density. Enlarge the rim of the hole to correspond to the outer diameter of the fixture's platform. Recommended speed setting is 1,200 rpm at 20Ncm (feed water). Profile drill should be used for D1-D2 Bone, but D3-D4 bone may be skipped with this step.

Profile Drill Unit: mr

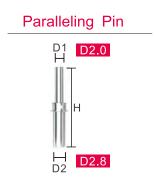


Name	Diameter (D)	Height(H)	Catalog No.	Fixture Ø
	D	24	3AA-065	3.5
Profile Drill	D	24	3AA-066	4.0
	D	24	3AA-067	4.5

- Used to trim the cortical bone with rotation speed 1,200rpm, torque 20Ncm, feed water; each drill corresponds to different diameters of fixtures
- Profile Drill
- Profile Drill Ø3.5 is used after Final Drill Ø2.8
- Profile Drill Ø4.0 is used after Final Drill Ø3.3
- Profile Drill Ø4.5 is used after Final Drill Ø4.0

Q12.0 What does parallel pin do?

A 12.0 Paralleling pin can be used as position point and can be used to inspect the occlusion and the distance of the implant with neighboring teeth. Instruction: Use white drill for 2.0 and use blue drill for 2.8



- Q13.0 Is there color marks on drill to distinguish for different implant size.
- A 13.0 There are colors mark on drill to differentiate the drills

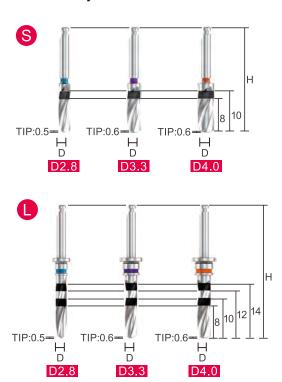
Color	White	Blue	Purple	Orange
drill				
diameter	D2.0	D2.8	D3.3	D4.0
Implant size	-	3.3/3.5/4.1	4.0/4.8	4.5/5.5



VIII. Regarding Surgical Instrument

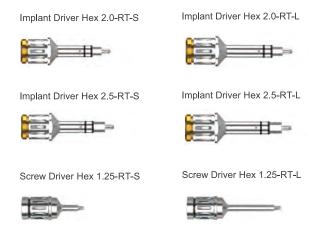
Q 14.0 What are the marked scales on Biomate Drill and what are the lengths of the tip?

A 14.0 Marked scales on the drill are 8.5/10.5/12.5/14.5; lengths of the drill tip are 0.5 or 0.6. Our sales pitch would say drill scales are 8/10/12/14 and drill tip length is 0.5



Q 15.0 What is the difference between Biomate implant driver and Screw driver? A 15.0 Golden heads are implant drivers (long and short), sliver heads are screw driver

(long and short)



Q 16.0 What is mount free design and how to take implant from fixture bottle? A 16.0 Biomate use mount free design (no mount)















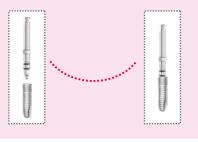
Note 1:

The hexagon and taper design of the fixture and the Implant Driver are made complimentary to each other. Gently press the Implant Driver to ensure it is firmly connected to the fixture before taking it out of the bottle.

Note 2: Hold the Implant Driver with the fixture upside down to prevent the fixture from contacting other matter or dropping

before placing it in the patient's mouth.

Note 3: Biomate implant has a mount free design.



Q17.0 Where can the cover screw be found in fixture bottle?

A 17.0 Cover screw is placed inside fixture bottle, need to remove the transparent cover, then use screw driver to counter rotate to take it out. (Remark: Not every brand pack screw with implant, such as ITI Straumann)









Use the Implant Driver with implant motor or torque ratchet to screw the fixture into the bone with recommended torque 35Ncm. When the fixture cannot be fully screwed in, assess the necessity of unscrewing the fixture. Verify the diameter of the hole before a second approach.

Note: Using excessive force to screw in the fixture may damage the bone and cause bone infarction due to excessive stress. It is recommended to unscrew the fixture and re-drill the hole.

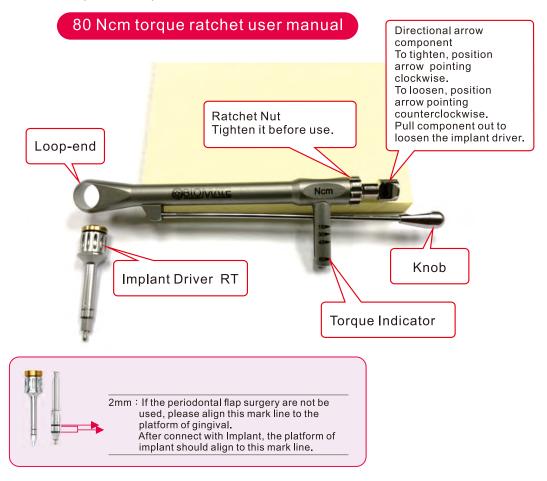


 Please turn Screw Driver Ø1.25-HP/RT(Ø1.25 hexagon key) counterclockwisely for 2 to 3 laps to take out the cover screw.

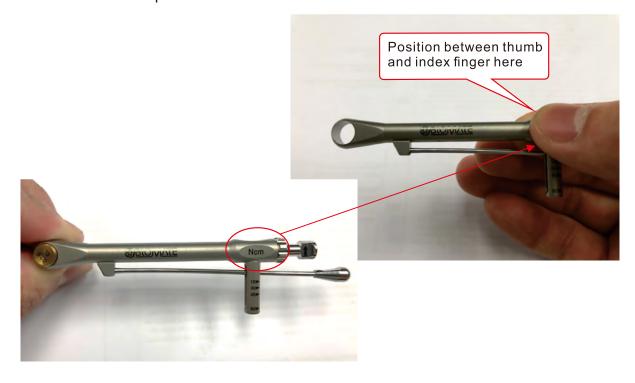


VIII. Regarding Surgical Instrument

- Q18.0 What are the black lines on implant driver designed for?
- A18.0 It is for minimally invasive surgery. It could provide a function to recognize the depth of implant insertion.



- Q19.0 How to use 80 Ncm torque ratchet user manual?
- A19.0 80 Ncm torque ratchet user manual:



80 Ncm torque ratchet user manual



Check directional arrow before use. To tighten, direction arrow must point clockwise (\psi). Pull it out to loosen implant driver.



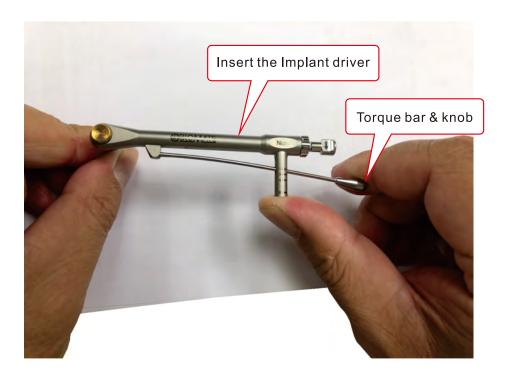
Check directional arrow before use. To loosen, direction arrow must point counterclockwise (†). Pull it out to loosen implant driver.

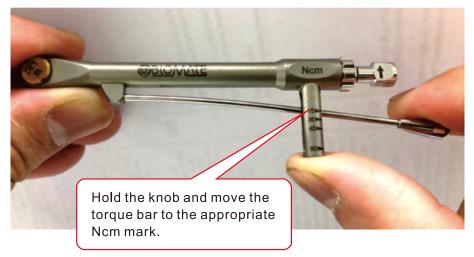


2-8

Q&AVIII. Regarding Surgical Instrument

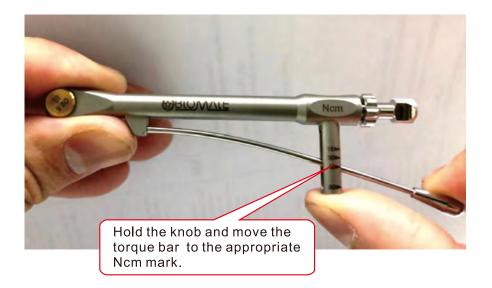
80 Ncm torque ratchet user manual

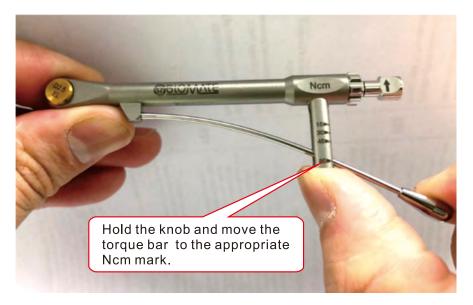






80 Ncm torque ratchet user manual









IX. Miscellaneous

- Q1.0 Can you provide the photo of your implant product?
- A1.0 Please refer to the photo below.





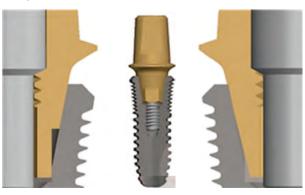




Q2.0 Please provide the sectional view for the connection interface between the implant and the abutment.

A2.0

Left: Simple Abutment Hex Middle: Implant sectional view Right: Simple Abutment Non-Hex



Q3.0 What certificates do you have? A3.0



















Q4.0 What helpful product information you can offer to understand Biomate implant system?

A4.0 Helpful Information in Google driver

I. Biomate Swiss

1. Introduction of BiomateSwiss:

https://drive.google.com/drive/folders/1x9A FOWSDLPCutCFVj hqkpzYcTHJ7-k?usp=sharing

2. BiomateSwiss Catalog:

https://drive.google.com/drive/folders/1EYUxvz1YNviuW7izPwcMLYZb508CT2ux?usp=sharing

3. BiomateSwiss (The Guidance)

https://drive.google.com/drive/folders/1WQGC7d0TwNMfAnVAlq hlnKrJo4aEM-P?usp=sharing

4. The demonstrations, why BiomateSwiss implant is unique

https://drive.google.com/drive/folders/1Di6Hd0x7uL0hU94BaC8upQkmPhamgDEe?usp=sharing

5. Research about Oxidation Layer

https://drive.google.com/drive/folders/1lgtHO2tnb1T_wwxzL_H-HPPbKjwQIXGt

6. Research about Cleanliness of BiomateSwiss implant

https://drive.google.com/drive/folders/1TyP3STCUNBsBscyoNpTkXVfflmmoggNZ?usp=sharing

7. Research about Surface firm

https://drive.google.com/drive/folders/1d0qsMthtlS6f20yi t1mtqbrf5irwrjO

8. BiomateSwiss Comparative Analysis:

https://drive.google.com/drive/folders/1xXiOZCxR4dI71f4f EEnyj tFlxHs0vy?usp=sharing

9. BiomateSwiss Anna's single diary (video):

https://drive.google.com/drive/folders/1m9bsCFImz5 rExKtw4xLa teazV3o4IM?usp=sharing

10. BiomateSwiss Brief description for each surgical kit:

https://drive.google.com/drive/folders/1heG4Q7dSFuLjMB4oZS1F5-t-TZLyr-Ys?usp=sharing

11. BiomateSwiss Total Solution:

https://drive.google.com/drive/folders/1XFYjeZeXimtWlgKMOrW-rhUgdWG4GfDN?usp=sharing

12. BiomateSwiss Post-Operative Care (Handbook)

https://drive.google.com/drive/folders/1PzMSK_zXDxrZVduhXI0frp5fMfDCD1Qn?usp=sharing

13. BiomateSwiss Protocols:

https://drive.google.com/open?id=1aoSTy174nFYGdh2-LXSLSH42gW0WAteW

14. BiomateSwiss Surgical Procedure (Video):

https://drive.google.com/drive/folders/1MBpj5UnHMD0Xh-TFB_SCdIRfILJ3sz2R?usp=sharing

15. BiomateSwiss Literature Review:

https://drive.google.com/open?id=1g-yFzwsdh9nWCAeLuGg9tEfJQw4mx-dn

16. BiomateSwiss Experiment Results Research Report:

https://drive.google.com/drive/folders/1ufBIIWPtz8LCz4ChtTKbFq5DAN_E17Q6?usp=sharing

17. BiomateSwiss Atlas of dental implant surgery:

https://www.biomate-device.com/atlas.htm

18. BiomateSwiss Atlas of dental implant surgery (video):

https://drive.google.com/drive/folders/1aGzyw0fnfzA9yaHpbfUaR3mtegALS0Mk?usp=sharing



II. 2021 Global Virtual Symposium

- 1. Presentation of Prof. Dr. Tao Chiang https://drive.google.com/drive/folders/1Sm2AJDgCLIR3HWMtllwiyKQiZJ2pGUWD?usp=sharing
- 2. Presentation of Dr. Andrei Cristian Ionescu https://drive.google.com/drive/folders/1Y2sV1OTXX2vaZJ7x0x9tG97eBT-0aoSi?usp=sharing
- 3. Presentation of Assoc. Prof. Dr. Amr Elkhadem https://drive.google.com/drive/folders/1xc_F08klKnhkGIGDqDjEV5vmqC03aEJa?usp=sharing
- 4. Presentation of Assist. Prof. Dr. Da Yo Yuh https://drive.google.com/drive/folders/1-A1_XpMBX9yqiyBUj7oTBitjkqYLV08h?usp=sharing

III. Others

- 1. Hands on course for Ghanaian doctors: https://drive.google.com/drive/folders/1MC2BBLNy6GsLZm9m1vLsgx4UpSqp6bRS?usp=sharing
- 2. Presentation of Prof. Dr. Tao Chiang PDL Laser Surface Treatment
 https://drive.google.com/drive/folders/1XfKL_h5aRaymj9rtj9UubSLUp_bna7jd?usp=sharing
- 3. Presention in Bangkok International Dental Implant Symposium 2019 https://drive.google.com/drive/folders/1NR3trJanjMPQrqKvdF87wvnYRowBNi0H?usp=sharing



Q5.0 Do you have videos about products or activities on YouTube?

A5.0

- 1. Product Information in videos on YouTube
- 1-1 Biomate PDL Surface Treatment Manufacturing Procedure https://www.youtube.com/watch?v=RFbGDZkJ i4
- 1-2 Biomate Dental Implant System-Blood Affinity Test
 https://www.youtube.com/watch?v=IW2XoZ0RHyc
 https://drive.google.com/file/d/1Odlk0wvdAWEUh4DJgdRPtVJtScLQcVN8/view
- 1-3 Biomate Mandibular Surgical Procedure of Biomate Implant System https://www.youtube.com/watch?v=QDIJWItrd9U
- 1-4 Biomate Mandibular Surgical Procedure of Biomate Plus Implant System https://www.youtube.com/watch?v=4GRFhmQBVSw
- 1-5 Biomate Mandibular Impression Procedure-Open-Tray Technique https://www.youtube.com/watch?v=htV86HWqXGQ
- 1-6 Biomate Mandibular Impression Procedure-Close-Tray Technique https://www.youtube.com/watch?v=gSZHIKq4FxE
- 1-7 The mount free design of Biomate Dental Implant System https://www.youtube.com/watch?v=BHJxpbj6lpk&list=PLccdblEC0om-dQ36-ehLlKpzLi_HfszoN
- 1-8 The mount free design of Biomate Dental Implant system for hand piece https://www.youtube.com/watch?v=Mb81jPqWPxI&index=2&list=PLccdbIEC0om-dQ36-ehLIKpzLi HfszoN
- 1-9 Dental Implant & Dental Bridge

https://www.youtube.com/watch?v=9PwKoencl30&feature=youtu.be

1-10 Biomate Osseointegration of Bone Cells

https://www.youtube.com/watch?v=eGQZJX0FTRQ&feature=youtu.be

1-11 Biomate sinus crestal approach kit

https://www.youtube.com/watch?v=gFC6LTNgpu4&feature=youtu.be

1-12 Biomate bone expender kit

https://www.youtube.com/watch?v=hN334NTibTI&feature=youtu.be

- 2. Video about Activities on YouTube
- 2-1 Biomate Company Profile

https://www.youtube.com/watch?v=gtoEt9e5dYg&t=85s

2-2 Biomate 2016 Activities

https://www.youtube.com/watch?v=gQ-C1MZVu04

2-3 Biomate 2017 Takao Forum of OMFS

https://www.youtube.com/watch?v=lfuldN TZIw&feature=youtu.be

2-4 Biomate 2017 Season 1

https://www.youtube.com/watch?v=yhx0Y8dYie4

2-5 2018 Biomate World Meeting Teaser

https://www.youtube.com/watch?v=5pzU1ubM2D4

- 2-6 Biomate Implant Academy Institute (IAI)- 2018 Sinus Lift Course https://www.youtube.com/watch?v=RiQh2Cm6Y0w&feature=youtu.be
- 2-7 Biomate International Symposium of Implant Dentistry 2018 https://www.youtube.com/watch?v=7tAMldq1LgA&feature=youtu.be



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