



UNIdental

 **Orcherstra**
Implant Academy

 **Symphony**
Implant System

We Make  Smile

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Symphony

Implant System

“
COMPANY INTRODUCTION
”



UNIdental GROUP

”

Symphony implant a product of UNIdental L.t.d company. UNIdental Develops and produces implant system more than 20 years. UNIdental co . , Ltd. Develops and produces a product with the motto of providing the best products and services by R&D professionals who have worked for research, development, and production of dental products and Implant-related areas Since 2002.



UNIdental

Symphony
Implant System

Symphony 2
Implant System

Orcherstra
Implant Academy

Symphony Kits

Symphony has been serving the dental field for the past 20 years by using the latest technologies and new innovations through research and development.

We have stood by quality all these years to serve you with our quality and reliable products. And we will continue to do so regardless of future competition. We're here to stay, always keeping up with developments in this rapidly evolving field of dental technology, and we greatly appreciate the recognition and trust you've placed in us.

By the grace of God as well as your loyalty and cooperation, we have reached great heights and are deeply committed to serve better in the future.

*Sincerely,
Richard Yang*



Symphony

Network 2025

AMERICA

-  United States
-  Mexico
-  Argentina

MIDDLE EAST

-  Saudi Arabia
-  Iraq
-  Pakistan

CIS

-  Russia
-  Uzbekistan

EUROPE

-  Hungary
-  Georgia
-  Albania
-  Norway
-  Turkey

ASIA

-  Korea
-  China
-  Vietnam
-  Thailand



Driven by exceptional feedback from dentists around the world, Symphony Implant continues to strengthen its global footprint. With sales and representation in nearly 20 countries, the brand is now strategically expanding its presence in the United States – bringing Korean innovation and precision to dental practices across the globe.





Management System Certification Body No. MSCB-105

CERTIFICATE

No. 20-B-0148 Rev. 1

UNIDENTAL Co., Ltd.

40613 GM technopark, 60 Haan-ro, Gwangmyeong-si, Gyeonggi-do,
14322, Republic of Korea

Company Reg. No.: 784-81-00432

has documented and implemented system in compliance with the requirements of

ISO 13485:2016

Medical Devices Quality Management System

for

Design & Development, Production and Sales of Dental Implant System

Technical Area: 84

The certificate is issued on the basis of the results mentioned in the pertinent audit report.
Validity of the certificate is conditionally limited by positive results of surveillance audits,
which the certified company is committed to undergo.

This certificate can be invalid if the certificate holder does not fulfill the conditions set out in
the certification agreement.

Initial issue date: Jan. 13, 2017
Re-issue date: Jan. 07, 2027
Expiry date: Jan. 11, 2027

G. Gilbert
G. Gilbert
Head of Certification Body



606, 6th, Daeyang-ro, Gwangmyeong-si, Gyeonggi-do,
14322, Republic of Korea
www.igc.or.kr



October 25, 2023

UNIDENTAL Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, California 92612

Re: K221315

Trade/Device Name: UNIDENTAL Symphony Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 29, 2023
Received: October 2, 2023

Dear Priscilla Chung:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

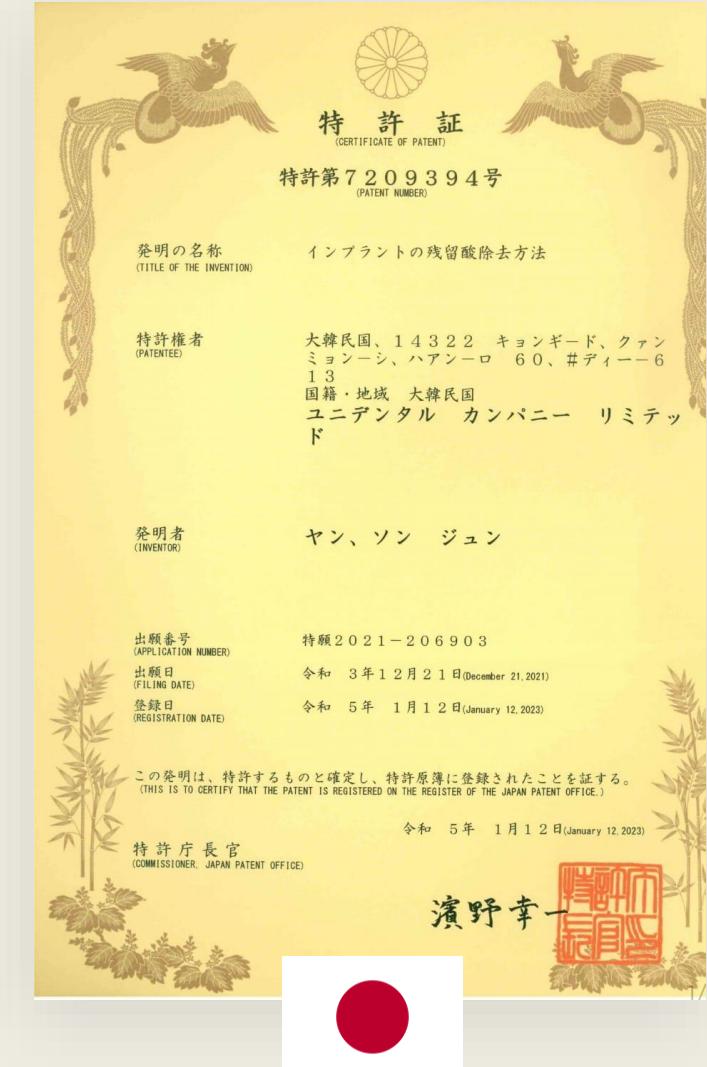
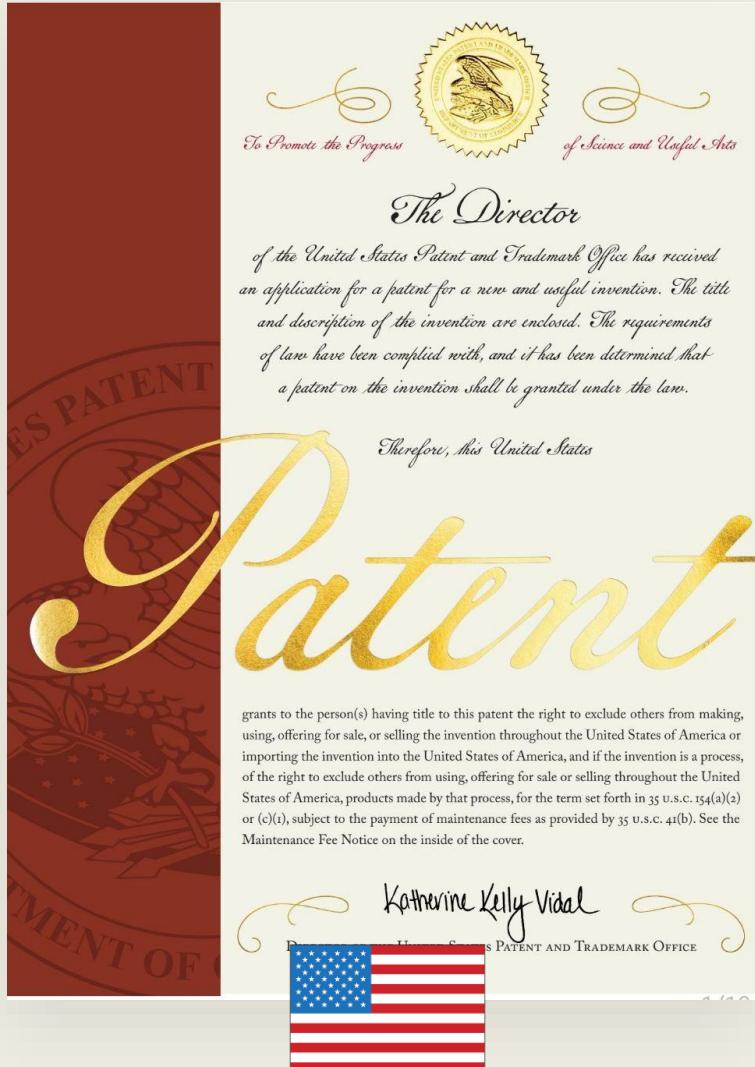
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

CERTIFICATES



Symphony
Implant System

PATENT CERTIFICATES



SYMPHONY

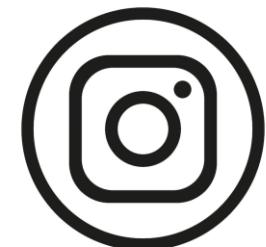
MANUFACTURING SITE

Symphony is focused on developing innovative and technologically advanced dental solutions, which improve patients' quality of life, and benefit dental professionals.





www.SymphonyImplant.com



SymphonyImplant

Symphony
Implant System



SYMPHONY 1

IMPLANT SYSTEM

BONE LEVEL
SUBMERGED TYPE



“
SYMPHONY IMPLANT
”

UNIdental GROUP

SYMPHONY 2

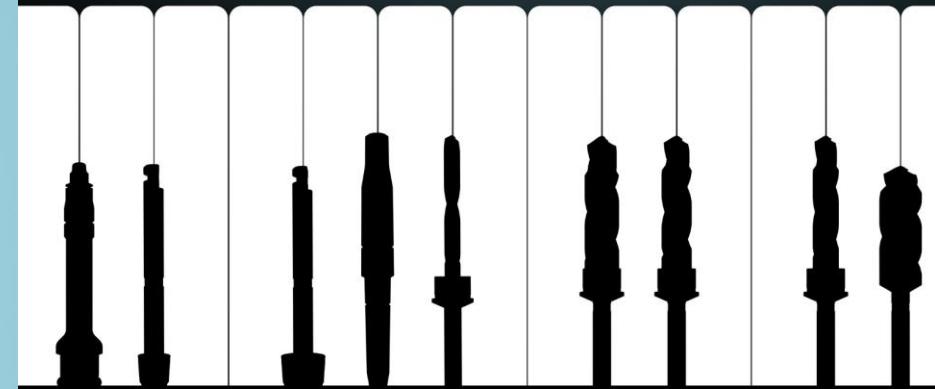
IMPLANT SYSTEM

TISSUE LEVEL
NON-SUBMERGED TYPE



SURGICAL KITS

KITS
INSTRUMENTS
DRILLING SEQUENCES





“ FIXTURE ”

US1 – Bone Level

US2- Tissue Level

Symphony

Implant System



OUR BEST Fixture

Symphony Implant System

Optimized Design for ANY SURGERY

- Simple surgical protocol helps reduce chair time
- Stabilized in use to Extraction Socket
- Enables Early Loading in upper posterior

Dual & Deep Thread

- Enhancing initial stability from deeply designed Thread
- Dual thread enables Fast insertion

Tapered Design

- Similar design of natural tooth
- Proper load distribution harmonized with anatomy

Interchangeable with hexagon morse tapered fixture

Sub Hexagon System

Titanium Grade 4

www.symphonyimplant.com

US1



Platform Switching

Help prevent crestal bone loss, increase the volume of soft tissue



SLA Surface

Surface of fixture is SLA (Sandblasting with Large grit and Acid etching)



Cutting edge

Cutting edge increase efficiency of implant in all bone types



Tapper Design

Tapper design help for primary stability & faster insertion while bone structure



Single Connection

The advanced conical hex connection between the fixture and abutments causes a decrease in bone loss & Screw Loosening



Morse & HEX

The single platform of prosthetic procedures with 11° degree in morse taper and 2.5 hex diameter



Double Thread

Increase bone to implant contact & Enable bone condensing properties & highest primary stability



APEX

The round apex reduces the risk of tissue damage, especially when placing the implant into maxillary sinus lift

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US1

		L (7.B)	L (7.0)	L (8.0)	L (10)	L (12)	L (14)
Fixture		3607B	3607	3608	3610	3612	3614
	D(4.0)	4007B	4007	4008	4010	4012	4014
	D(4.5)	4507B	4507	4508	4510	4512	4514
	D(5.0)	5007B	5007	5008	5010	5012	5014
	D(6.0)	6007B	6007	6008	6010	6012	
	D(7.0)	7007B	7007	7008	7010	7012	

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US1-3607B



US1-4007B



US1-4507B



US1-5007B



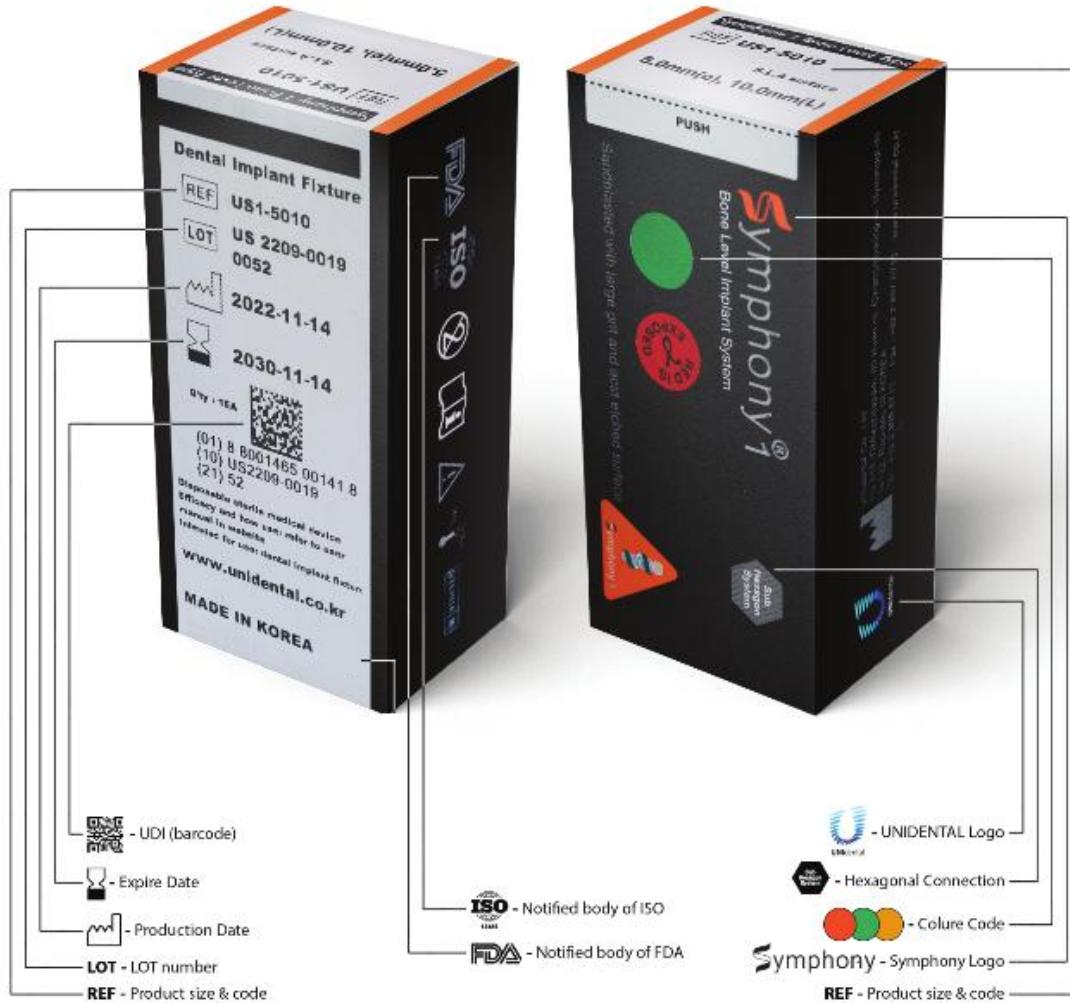
US1

SHORT IMPLANT

Symphony
Implant System

UNIdental GROUP

US1



Symphony
Implant System

UNIDENTAL GROUP

Symphony

Implant System



OUR BEST Fixture

Symphony
Implant System

Flowing and smooth neck design

- Optimized for 1 stage surgery
- Optimal cuff design promotes fast tissue recovery
- Proper load distribution of prosthesis enhances success rate

S.L.A. Surface

- Excellent structure of Macro & Micro through
- Proven process of Blasting & Etching
- Fast osseointegration and predictable results
- World professional concede the performance

Internal Octa & 8° Taper Connection

- Single prosthetic connection
- Applicable to all fixture size
- Compatible with ITI type prosthesis

Interchangeable with Octagon fixture

Non-Sub Octagon System

www.symphonyimplant.com



SURFACE TREATMENT

“ **SLA** ”

Sand-blasted, Large grit, Acid- etched

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Implant System

SYMPHONY Surface

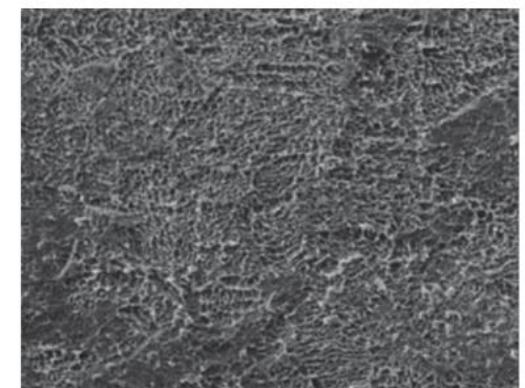
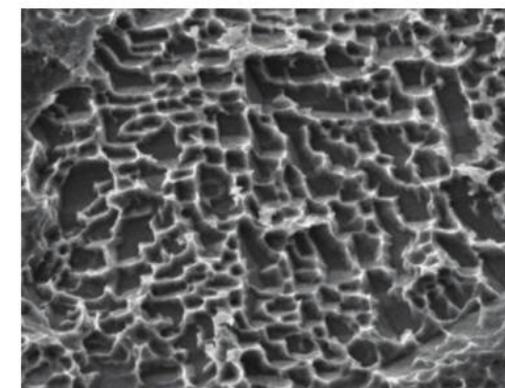
- Higher BIC (Bone to Implant Contact)
- Faster and Stronger Osseointegration

Optimal surface through Acid etching Ideal surface RA 2.0~3.0 μ m

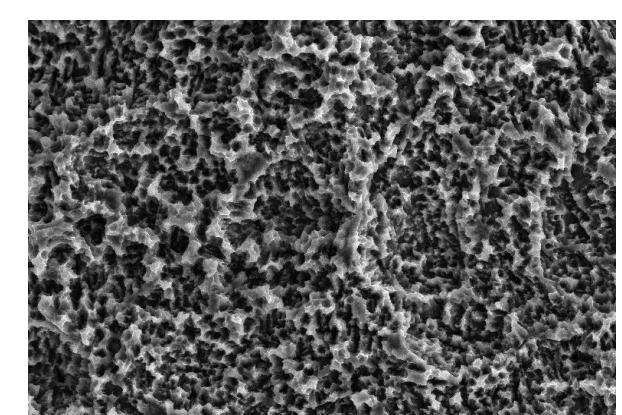
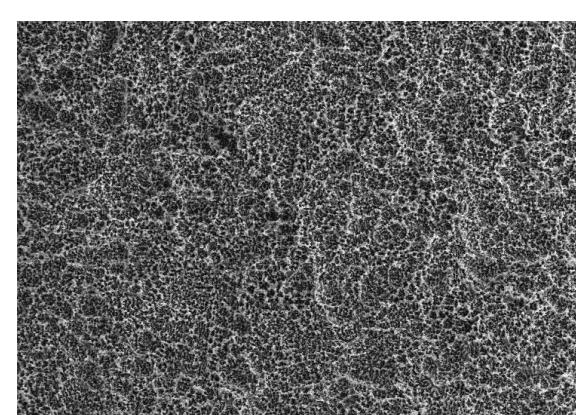
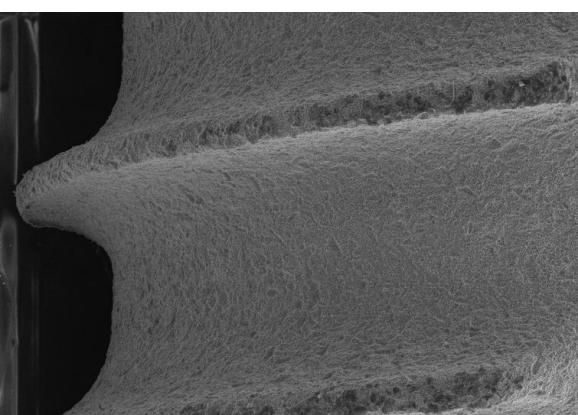
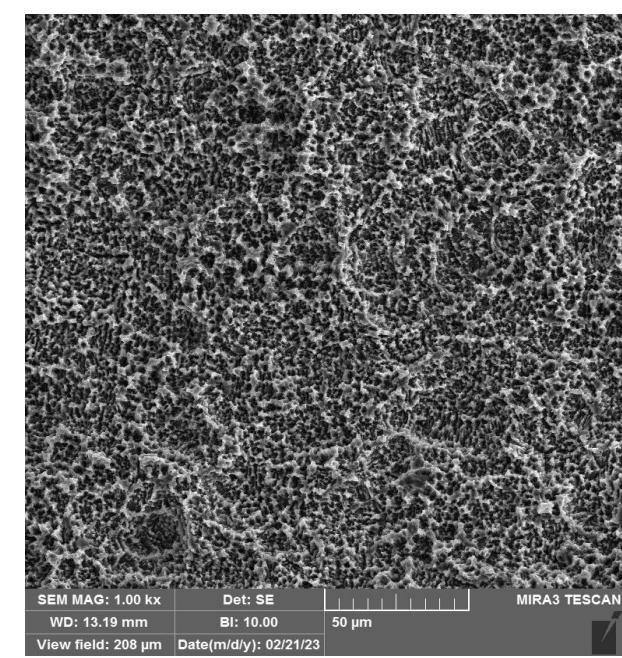
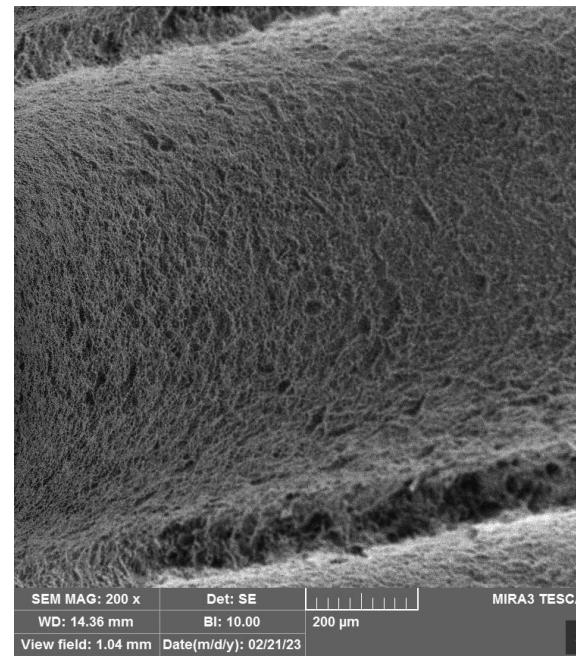
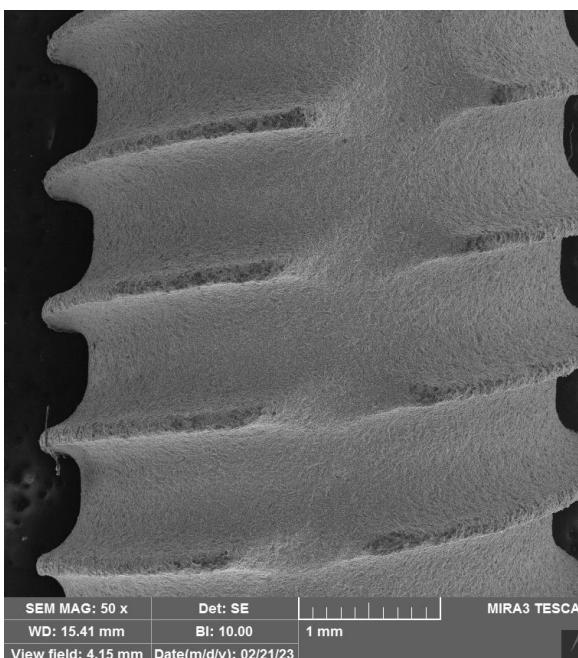
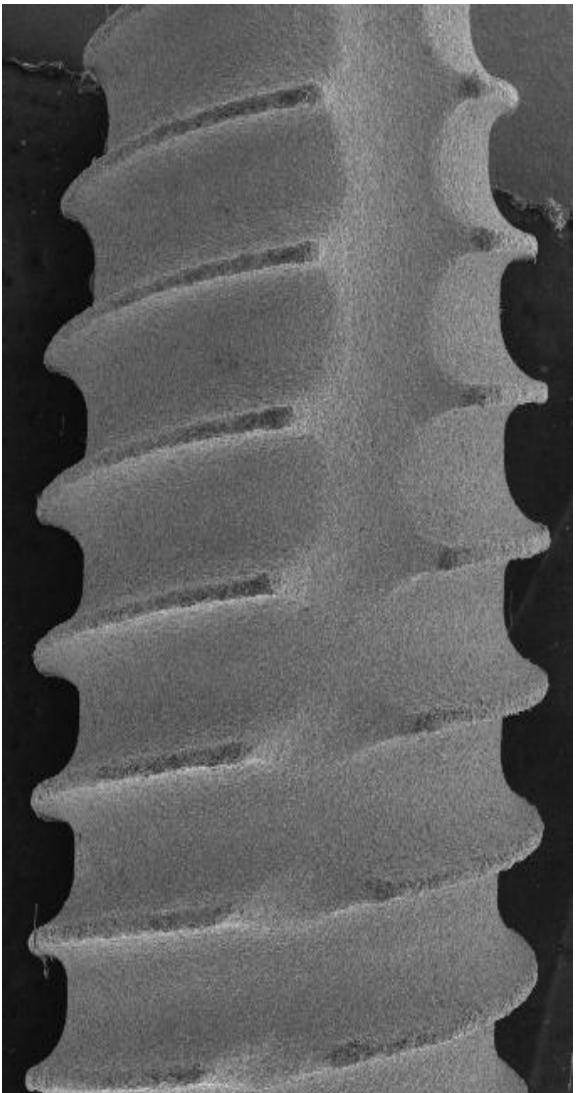
- More 45% surface area than RBM
- More than 20% enhanced activation of Osteoblast & Bone formation than RBM

Superior Osseointegration In-vivo experiment [mini-pig]

- Enhanced 45% of early fixation against RBM
- Enhanced 20% of new bone formation against RBM [BIC, 4wks]



SEM image of SYMPHONY fixture



SYMPHONY SLA Surface



Symphony[®] Kits

Surgical Implant Kits

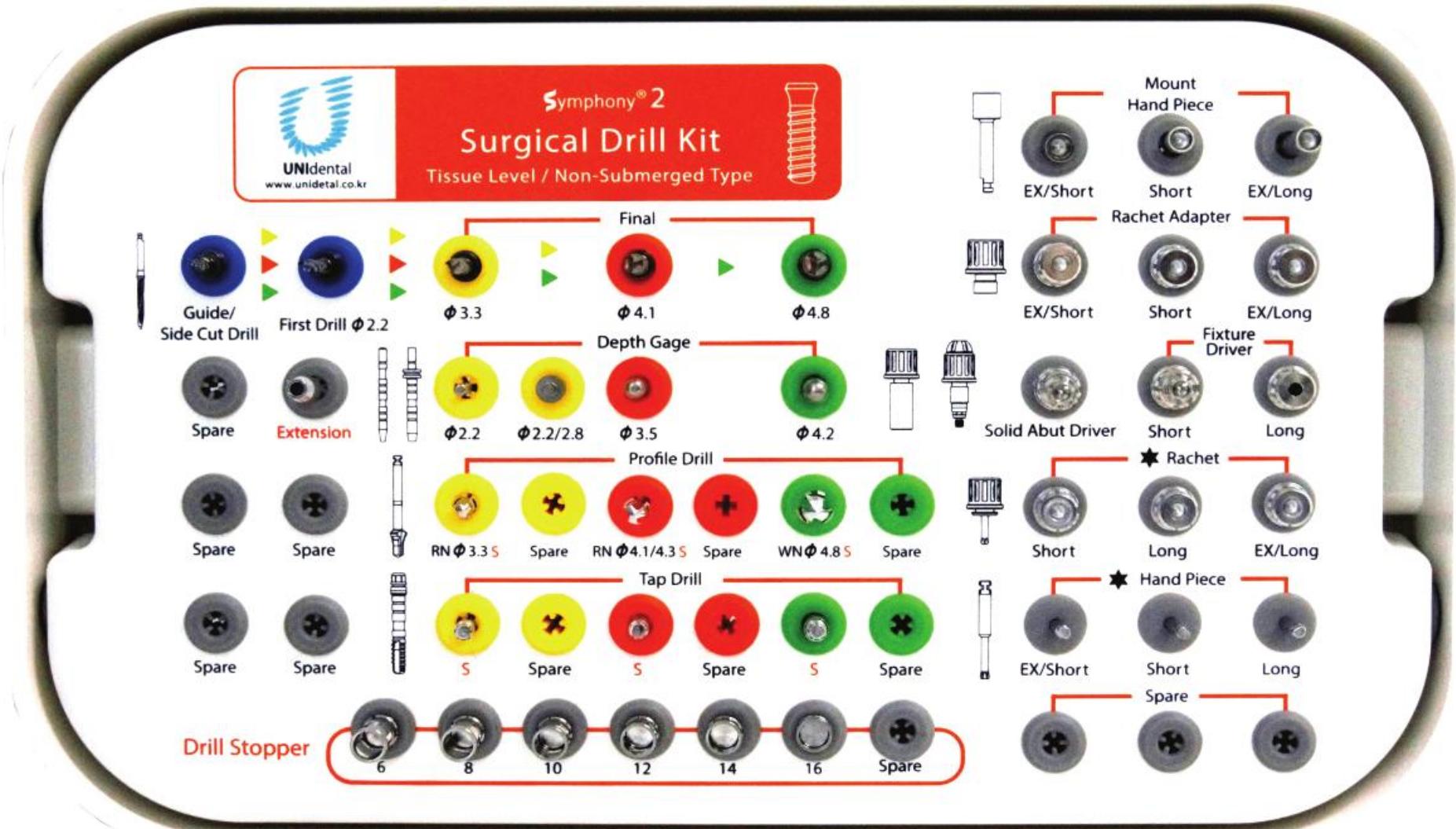
Symphony 1 | Symphony 2 | Prosthetic



Symphony 1 Surgical kit

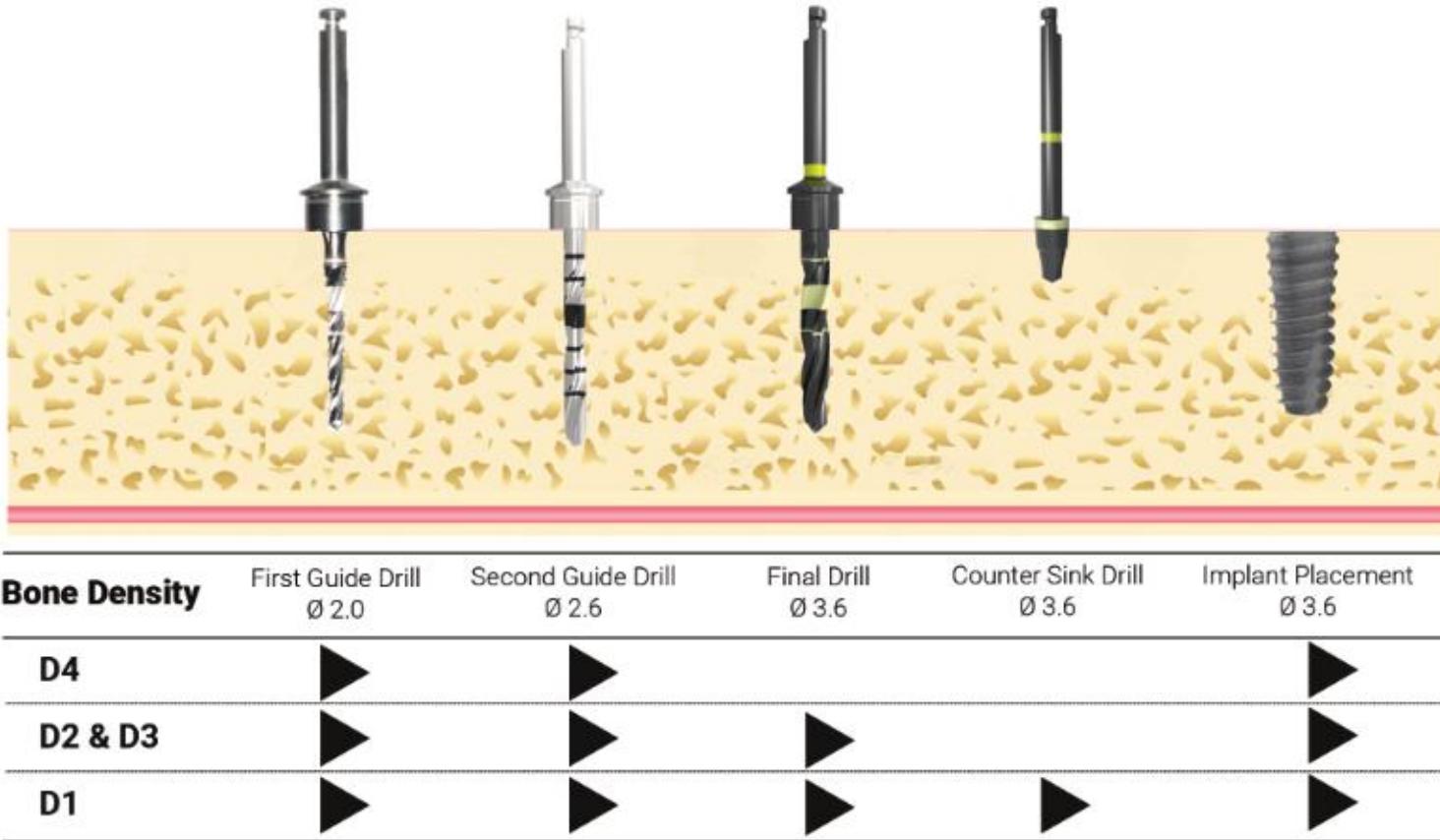


Symphony 2 Surgical kit

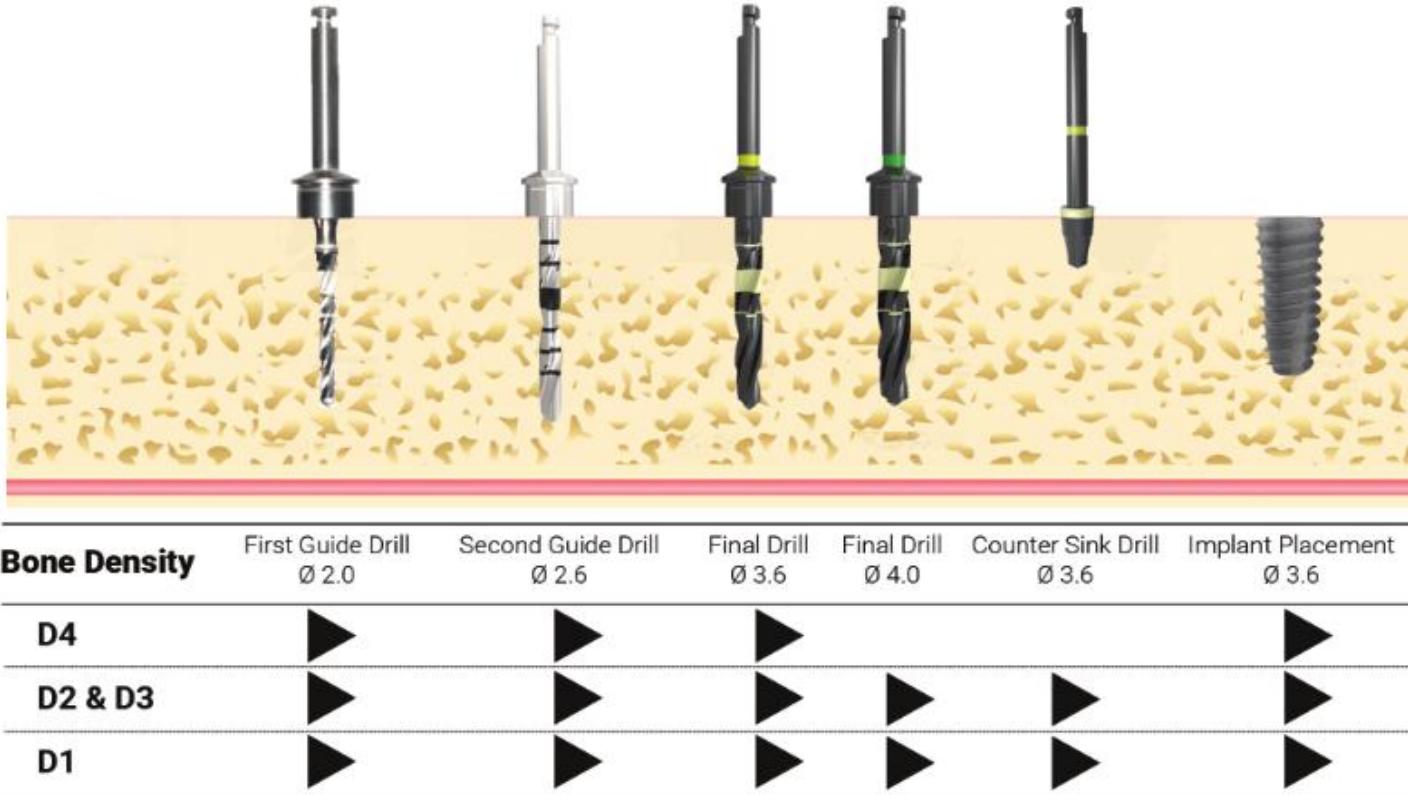


Symphony All Surgical Kit



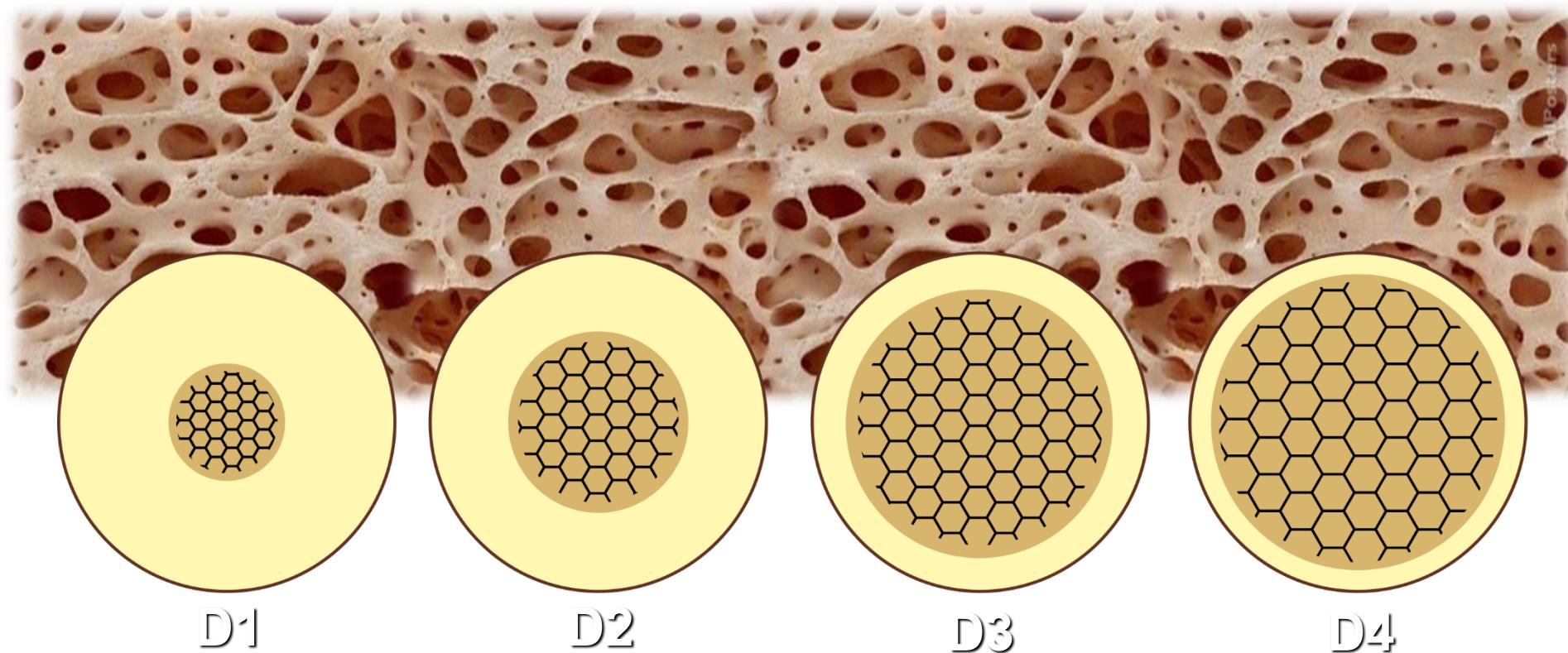


| Diameter Ø 3.6



| Diameter Ø 4.0

BONE QUALITY



Bone classification: clinical-histomorphometric comparison.

Trisi P, Rao W.

Clin Oral Implants Res. 1999 Feb;10(1):1-7. doi: 10.1034/j.1600-0501.1999.100101.x.

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“ Clinical case ”

Symphony 1
Implant System



Clinical Case

Symphony 1
Implant System



CASE 1



Pre implant

Implant surgery

Final prosthesis

Follow up 3yrs

- **Patient Specifications:** Gender: Male / Age: 42 years old /
- **Packaging and order:** No systemic disease
- **Implant treatment specifications:** Implant area: 7 lower right / Implant size: 4012

CASE 2



Pre implant

Implant surgery

Final prosthesis

Follow up 4yrs

- **Patient Specifications:** Gender: Female / Age: 39 years old /
- **Packaging and order:** No systemic disease
- **Implant treatment specifications:** Implant area: 5 and 6 lower left and 6 lower right / Implant size: 3 pcs. 4010



CASE 3

- **Patient Specifications:** Gender: Male / Age: 71 years old /
- **Packaging and order:** high blood pressure, heart disease and diabetes
- **Implant treatment specifications:** Implant area: 1, 3 and 6 upper right, 4, 5 and 6 lower left / Implant size: 4 pcs 3610 and 2 pcs 3612



Pre implant

Implant surgery

Final prosthesis

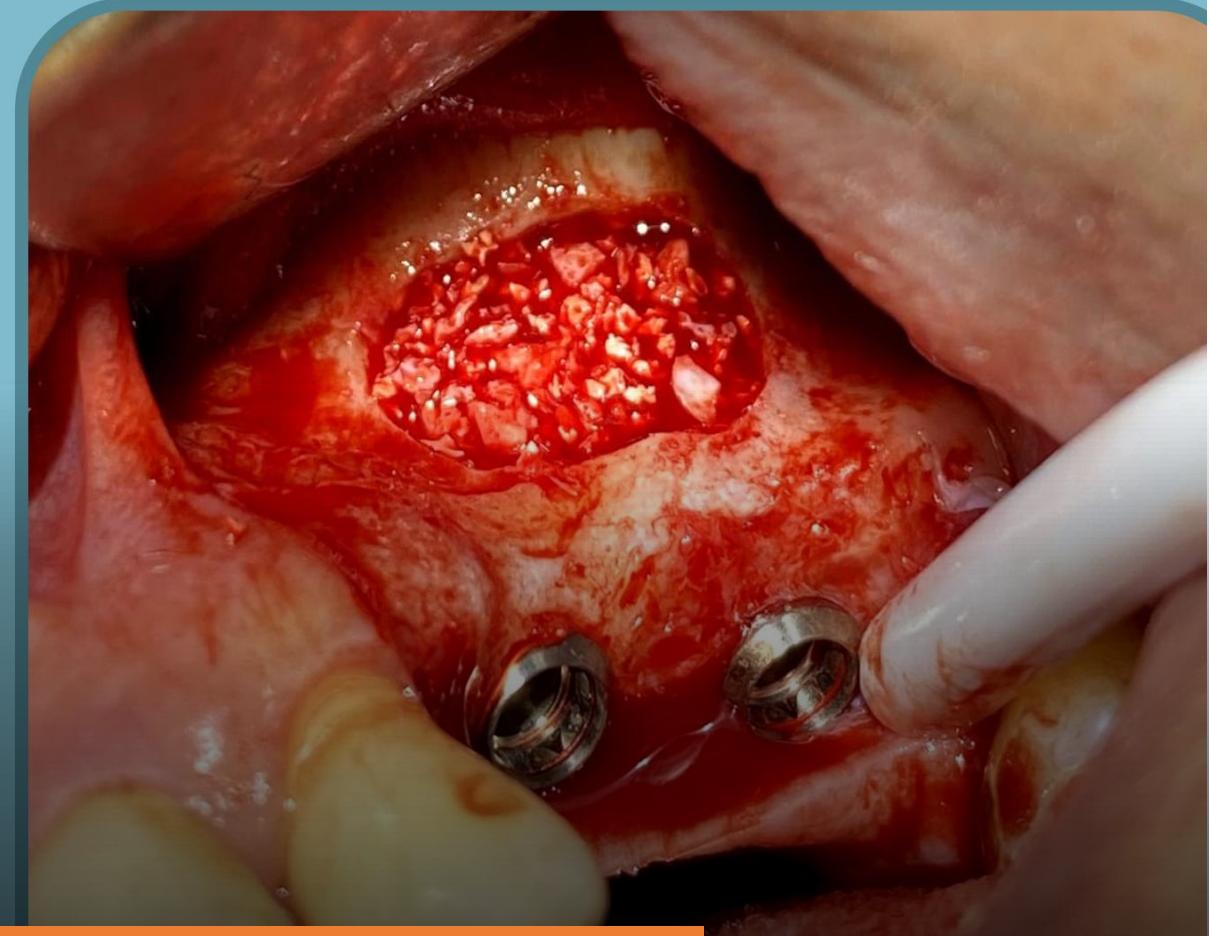
Follow up 5yrs

Symphony2
Implant System



Clinical Case

Symphony2
Implant System



Prosthetic Procedure II

SYMPHONY
PROSTHETIC

**Multi
Temporary
Abutment**
Hex/Non-Hex
US1MT-4815H



**CCM
Abutment**
Hex/Non-Hex
USML-48



**Multi
Straight
Abutment**
US1DA-4725H



**Multi
Angled
Abutment**
US1MA-481710H



**Multi
Analog**

US1MC-4815H



**Multi
Impression
Coping**

USMI-P4811



**Cover
Screw**

US1CS-36

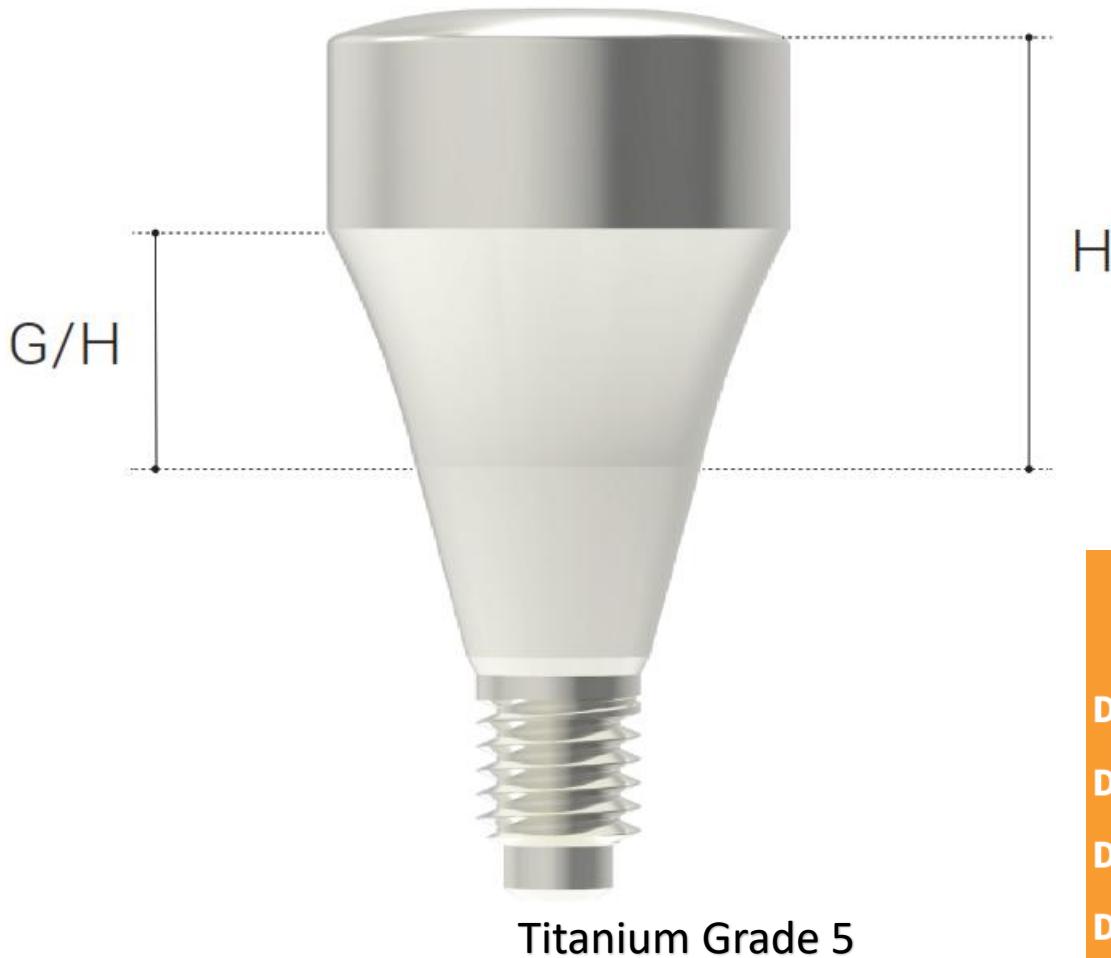


**Healing
Abutment**

US1HA-454070



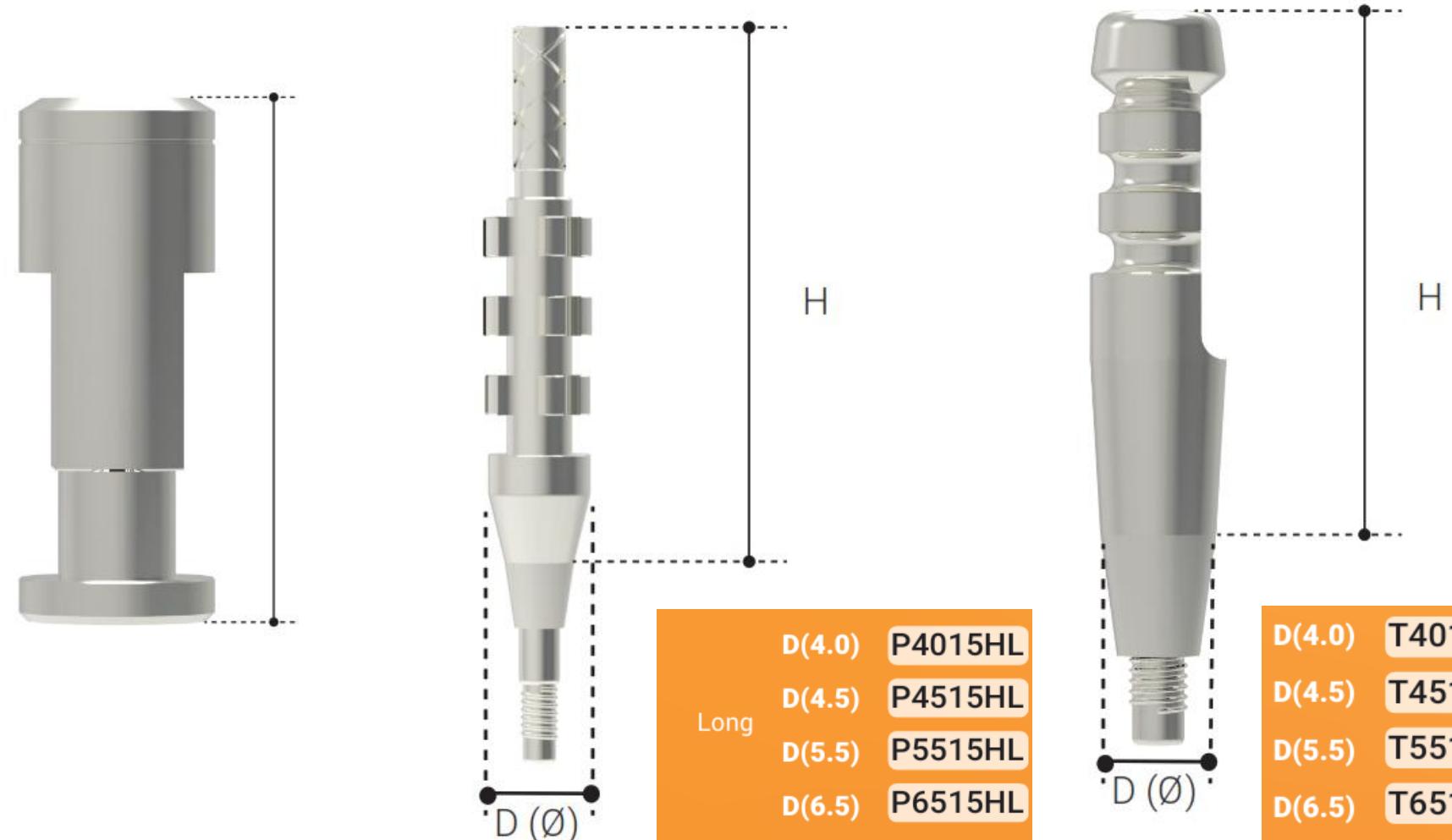
Healing abutment



	GH (2.0)	GH (2.0)	GH (3.0)	GH (4.0)
	H (2.0)	H (3.5)	H (5.0)	H (7.0)
D(4.0)	402020	402035	403050	404070
D(4.5)	452020	452035	453050	454070
D(5.5)	552020	552035	553050	554070
D(6.5)	652020	652035	653050	654070
D(7.5)	752020	752035	753050	754070
D(8.5)	852020	852035	853050	854070
D(9.5)	952020	952035	953050	954070

Analog impression

Titanium Grade 5



Long

D(4.0) P4015HL

D(4.5) P4515HL

D(5.5) P5515HL

D(6.5) P6515HL

Short

D(4.0) P4011HS

D(4.5) P4511HS

D(5.5) P5511HS

D(6.5) P6511HS

D(4.0) T4015HL

D(4.5) T4515HL

D(5.5) T5515HL

D(6.5) T6515HL

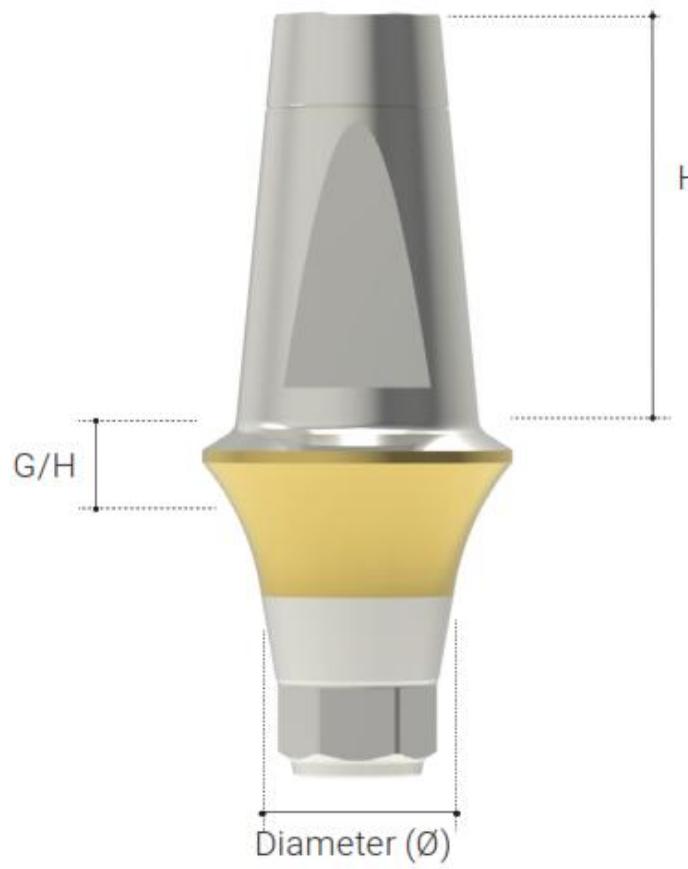
D(4.0) T4011HS

D(4.5) T4511HS

D(5.5) T5511HS

D(6.5) T6511HS

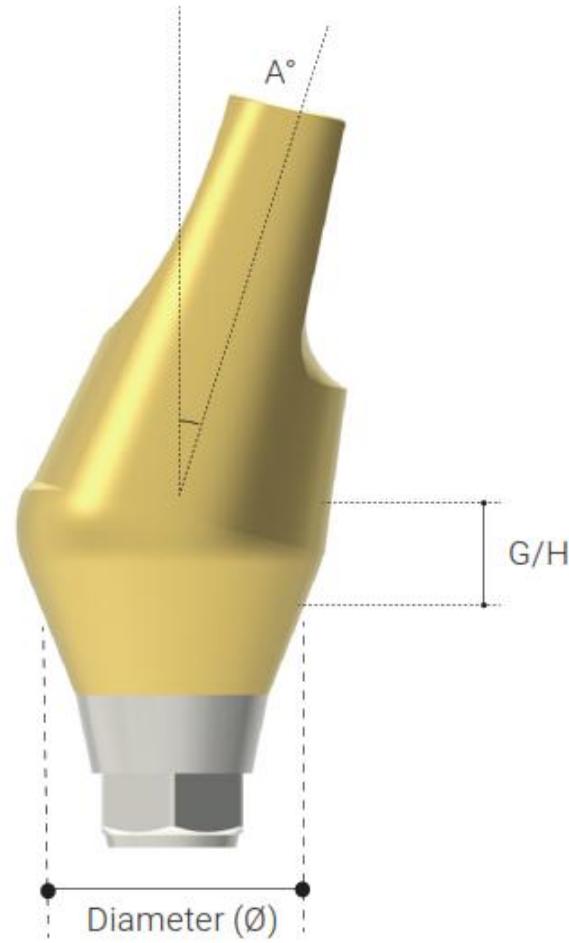
Straight Abutment



Coding Sample : US1DA-5725H
Titanium Grade 5

		GH (1.5)	GH (2.5)	GH (3.5)	GH (4.5)	GH (5.5)
D(4.5)	5.5	4515H	4525H	4535H	4545H	4555H
	7.0	4715H	4725H	4735H	4745H	4755H
D(5.5)	4.0	5415H	5425H	5435H	5445H	5455H
	5.5	5515H	5525H	5535H	5545H	5555H
D(6.5)	7.0	5715H	5725H	5735H	5745H	5755H
	4.0	6415H	6425H	6435H	6445H	6455H
	5.5	6515H	6525H	6535H	6545H	6555H

angel Abutment

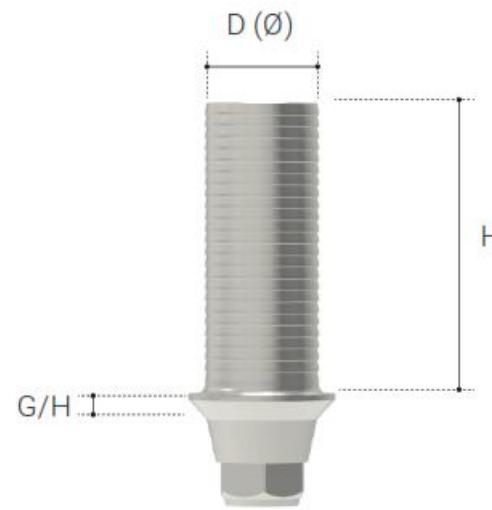


Coding Sample : U1AA-551525H

Titanium Grade 5

Symphony
Implant System

		GH (1.5)	GH (2.5)	GH (3.5)
D(4.5)	15°	451515	451525	451535H
	25°	452515H	452525	452535H
D(5.5)	15°	551515H	551525H	551535H
	25°	552515H	552525H	552535H



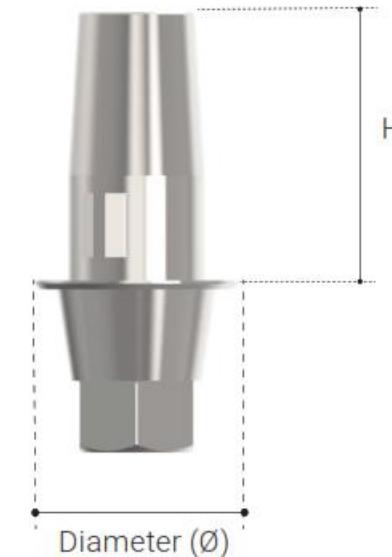
Coding Sample : US1TA-4515H

TEMPORARY ABUTMENT



Coding Sample : US1CA-4510H

CCM ABUTMENT



Coding Sample : US1TB-4546RN-L

Ti-Base ABUTMENT

Muti Straight ABUTMENT



US1MA-4810N

Muti Angled ABUTMENT



Coding Sampling :US1MA-4825N

Muti Temporary ABUTMENT



US1MT-4815N

Muti CCM ABUTMENT



US1MC-4815N

Muti Analog

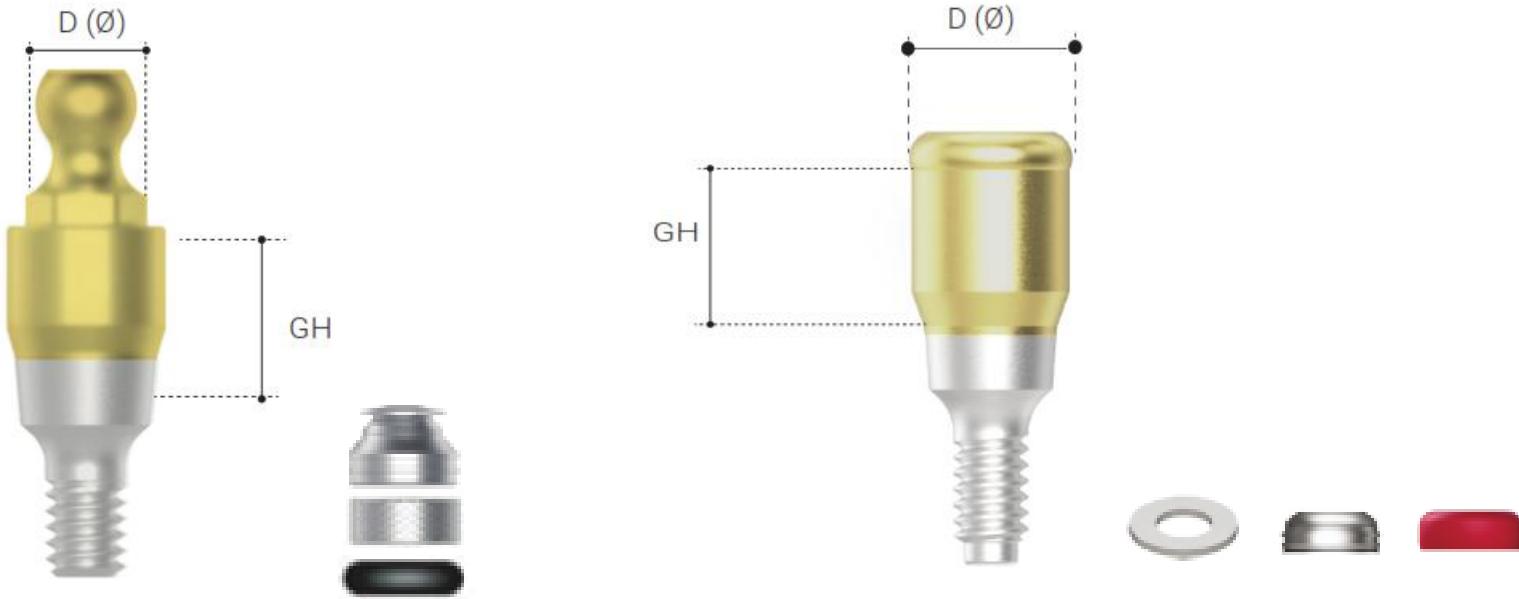


Coding Sample :USML-48

Muti Imperssion



Coding Sample : USMI-P4811



Coding Sample : US1BA-3550

Ball Abutment



	$D (3.5)$
GH(0.0)	3500
GH(1.0)	3510
GH(2.0)	3520
GH(3.0)	3530
GH(4.0)	3540

US1BA

Ball Attachment



Housing Retainer O-ring
US1HO-50 US1RE-50 US1OR-50

Kerator Abutment



	$D (3.7)$
GH(1.0)	3710
GH(2.0)	3720
GH(3.0)	3730
GH(4.0)	3740
GH(5.0)	3750

US1KA

Kerator Attachment



US1KS Kerator set **US1KS**

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