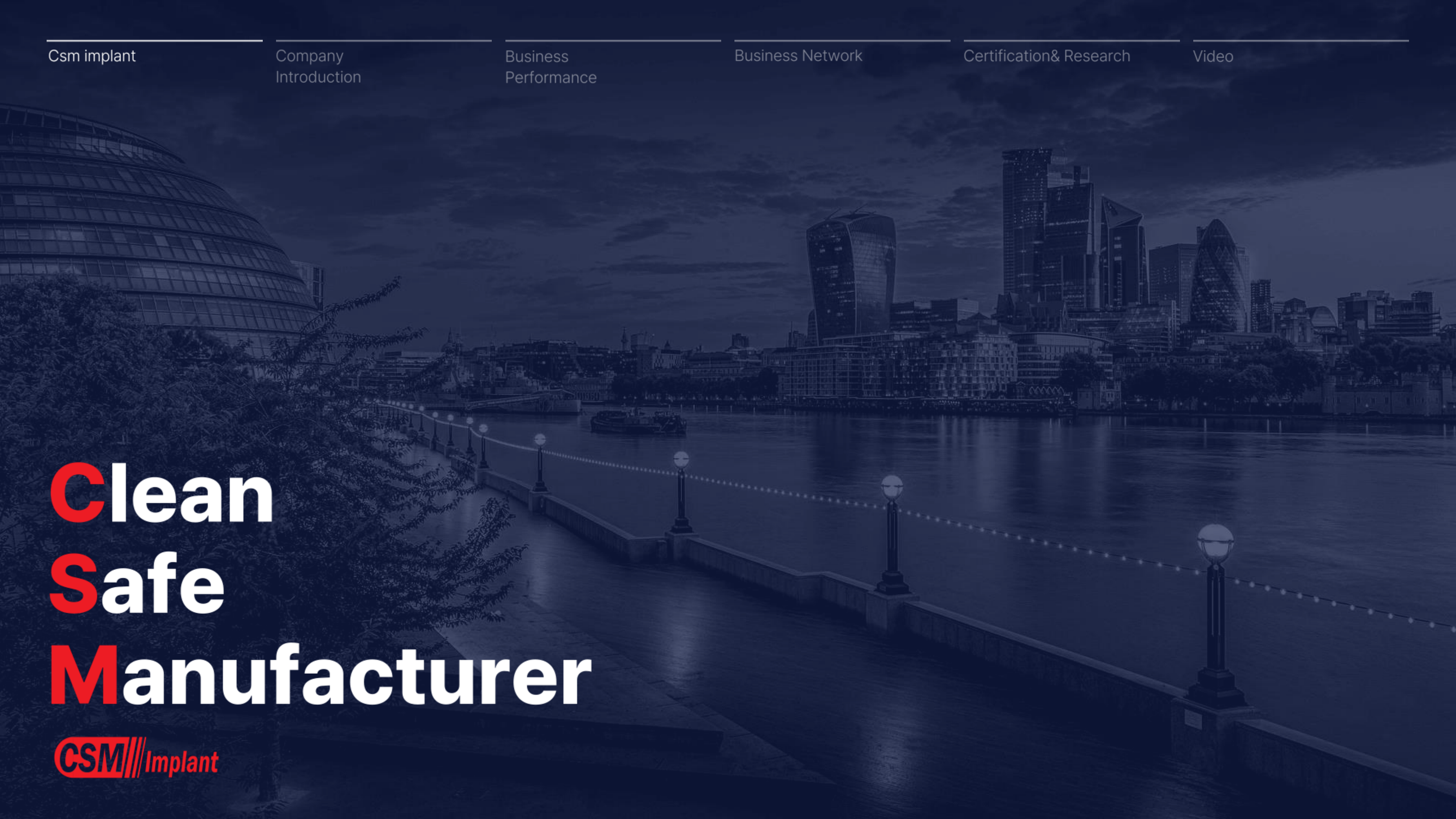
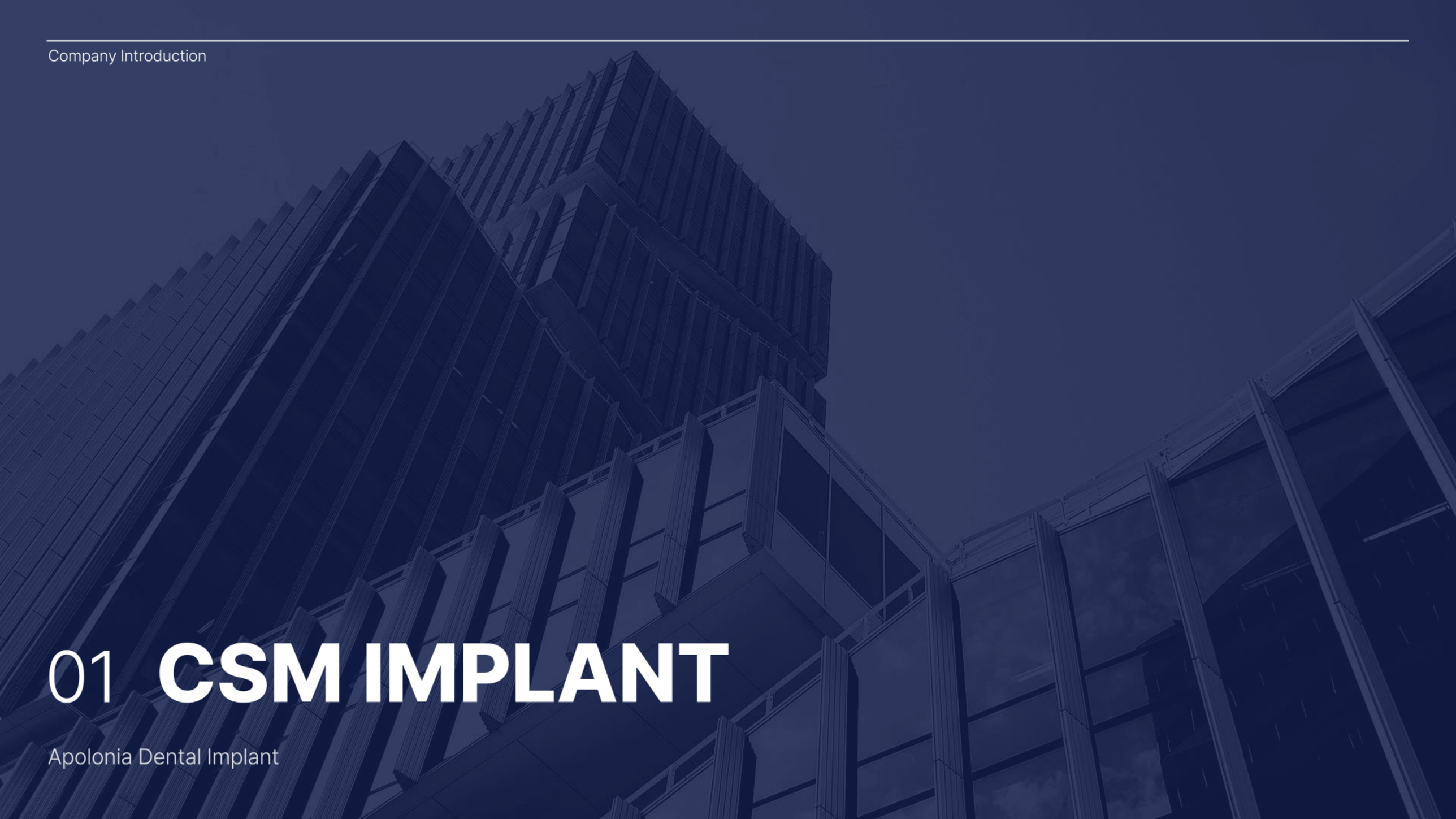


Clean Safe Manufacturer

CSM Implant

Table of Contents



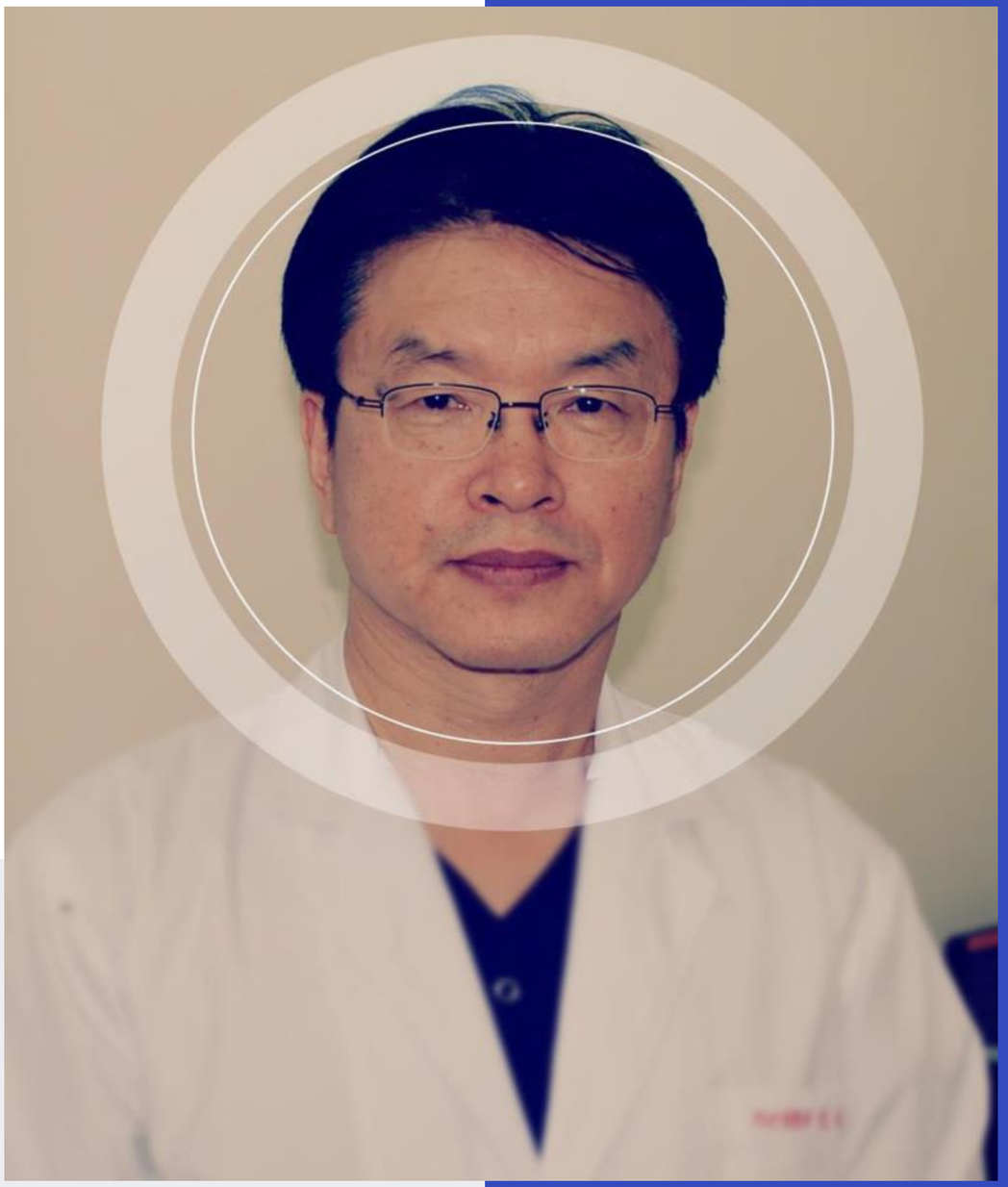
01 CSM IMPLANT

Apolonia Dental Implant

CSM IMPLANT CEO

CEO Jo Sung-am took the Seoul National University College of Dentistry course.
After graduation, he worked as a professor in the Department of Prosthetics at Kyungpook National University.
He has been involved in dentistry for 40 years.
Also, as a first-generation student studying implant in Sweden,
He is a pioneer in introducing implant surgery for the first time in Korea after returning to Korea.
As a dentist and professor of dentistry,
Based on the rich experience gained through actual surgery and research, we provide products that dentists can use conveniently, CSM Implant was born by researching to make a product that patients can trust.

CSM IMPLANT | CEO SUNG-AM CHO



01
Dental Implant

It is a medical device that restores the masticatory power of edentulous patients and treats esthetic defects.
As a major product for dental implants, CSM's craftsmanship stands out.

02
Dental Supplies

Abutment: The part that completes the artificial tooth together with the implant.
Impression product: This product is used to imitate the oral structure.

03
Surgical Kit

Surgical Kit: It is a medical surgical kit used for implant procedures.
Assistance kit: It is an auxiliary surgical tool used during or after implant procedures.

Company introduction

Name CSM IMPLANT

CEO SUNG-AM CHO

Number of Employees 18

Headquarters B205,B201 Techno B/D Kyungbook Uni, 47, Kyeongdae-Ro 17Gil, Buk-Gu, Daegu, Korea

Date of establishment. 2000.01.24

Contents of the business. Manufacture Dental implant

Produced products. Dental Implant

" CSM IMPLANT MOTO "

CLEAN

SAFE

MANUFACTURER

COMPANY BELIEF

Since its establishment on January 24, 2000, it is a manufacturer that has specialized in producing implants for about 20 years.
Based on 20 years of know-how, we produce and provide clean and safe products. With the goal of maximizing customer satisfaction,
All the staff members are working hard to do their best.

CSM HISTORY

2000.01.24	Company Estabilished (CEO : Sung-Am Cho)
2004.05	Acquired CE, ISO 13485
2007.04	Acquired KGMP
2009.10	Acquired Russian FDA
2010.03	Acquired R&D Center Qualification
2011.03	Acquired R&D Center Qualification
2012.06	Designated as a promising export company ny Daegu Gyeongbuk Export Center
2013.11	Acquired CFDA from China food and Drug Administration
2014.06	Acquired India CDSCO
2019.01	Acquired ISO 13485: 2016
2020.04	Acquired a Research Department Certification
2020.05	Acquired Taiwan Food and Drug Administraion TFDA
2020.07	Acquired a Certificate of Designation as a Promising Export Small Business
2021.04	Obtained Iranian Ministry of Health (MOH) License

02 Product Discription

FIXTURE

Submerged 1

Micro Threads : 6 lines
Body Threads : 3 lines
Connection:
2.1 Double Hex / 2.5 Hex

Submerged 2

Micro Threads : 6 lines
Body Threads : 3 lines
Connection:
2.1 Double Hex /
2.5 Double Hex

Submerged 3

Micro Threads : No
Body Threads : 3 lines
Connection:
2.1 Double Hex / 2.5 Hex

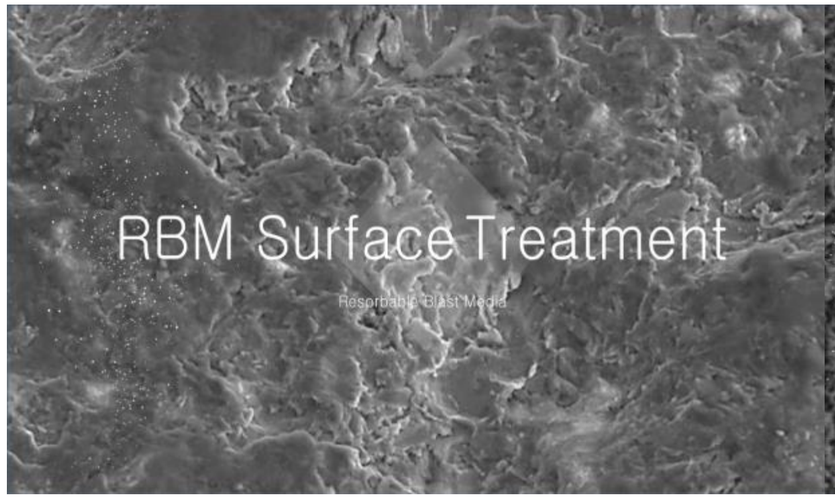
Internal

Micro Threads : 3 lines
Body Threads : 3 lines
Connection: 3.1 Octa

External

Micro Threads : No
Body Threads : 3 lines
Connection: 2.7 Hex

3 TYPES OF SURFACE



Resorbable Blast Media

RBM Roughness of Ra 1.5 ~ 1.8 µm

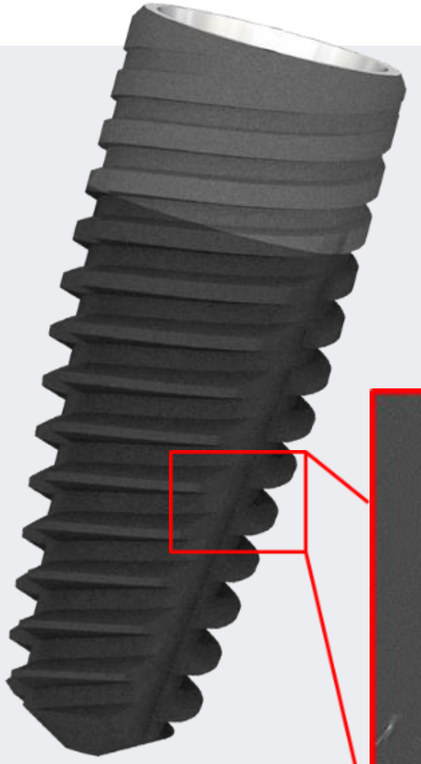
Sand Blasted, Larger Grit, Acid Etched
SLA Roughness of Ra 2.0 ~ 2.3 µm

Dual Surface Treatment

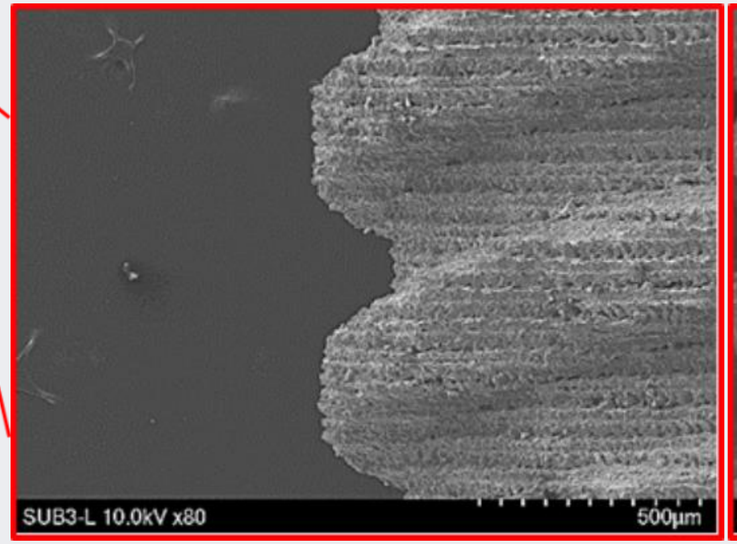
LASER Roughness of Ra 10 ~ 12 µm

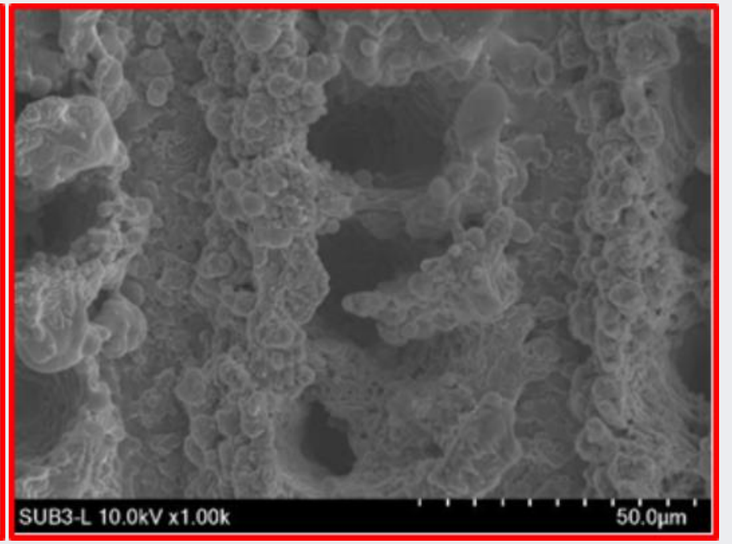
The Strengh of the Product

1. Strong Osseointergration



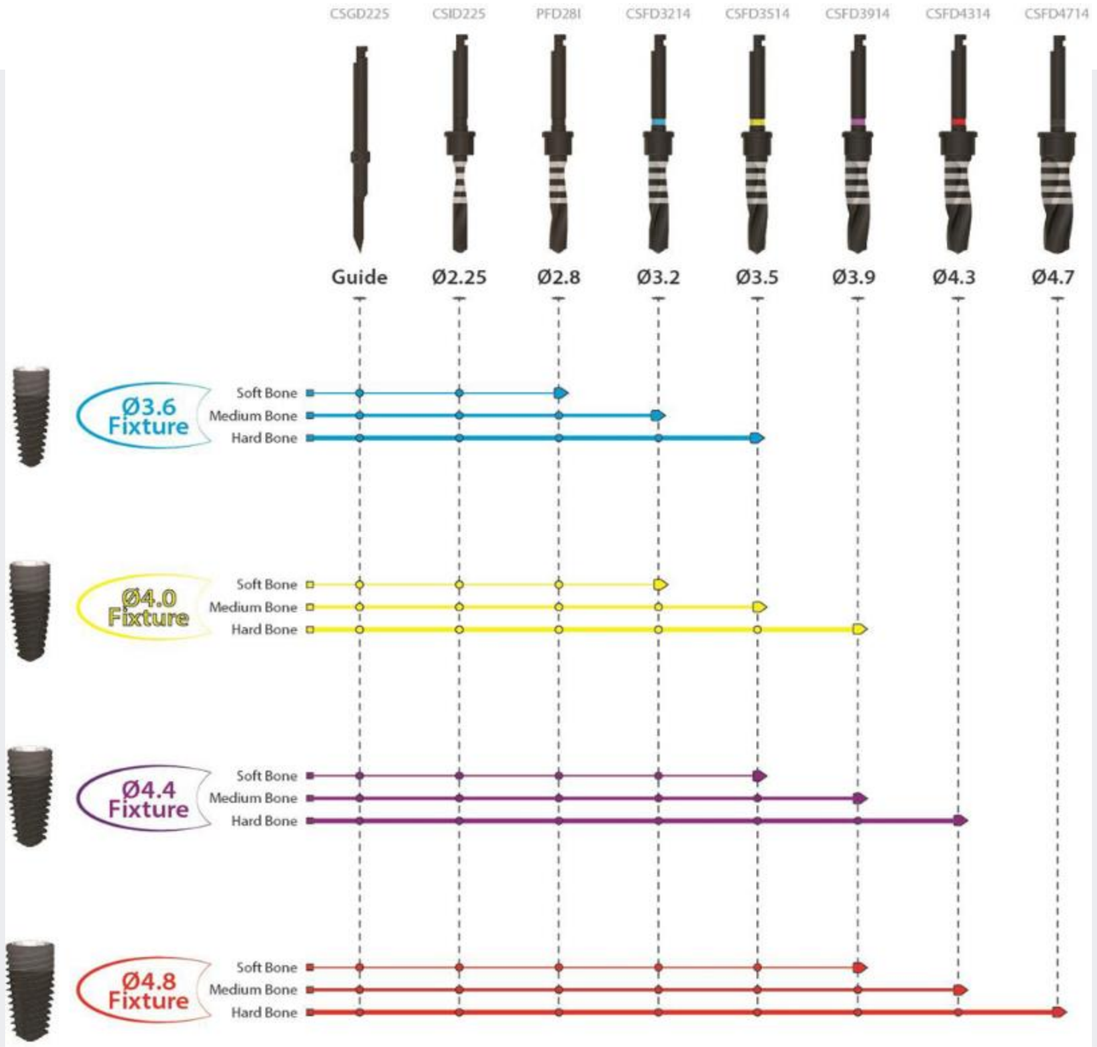
Lasder Surface Treatment
Roughness of Ra : 10 µm ~ 12 µm
Excellent Secondary Stability





The Strengh of the Product

2. Convenient and Fast Operation



The Strengh of the Product

3. Compatible with Submerged System

Ø4.0 Implant
Ø4.4 Implant
Ø4.8 Implant
2.5 Hex

Ø3.6 Implant
2.1 Double HEX Compatible
with Sub1 Ø3.5 Fiture

CSM Fixture Compatibility Chart

CSM	OTHERS	Astra	Ossetem	Dentium	Dentis	Dio	Megagen
Submerged 1 Submerged 3 Fixture	2.1 Double Hex	Aqua (Ø3.5/Ø4.0)	X	X	X	X	X
	2.5 Hex	X	GS, TS (EXCEPT Ø3.4/Ø3.7 FIXTURE)	Implantium SuperLine	S-Clean	UF, UF2	Anyone
Submerged 2 Fixture	2.1 Double Hex	Aqua (Ø3.5/Ø4.0)					
	2.5 Double Hex	Lilac (Ø4.5/Ø5.0)					

03 Business Network

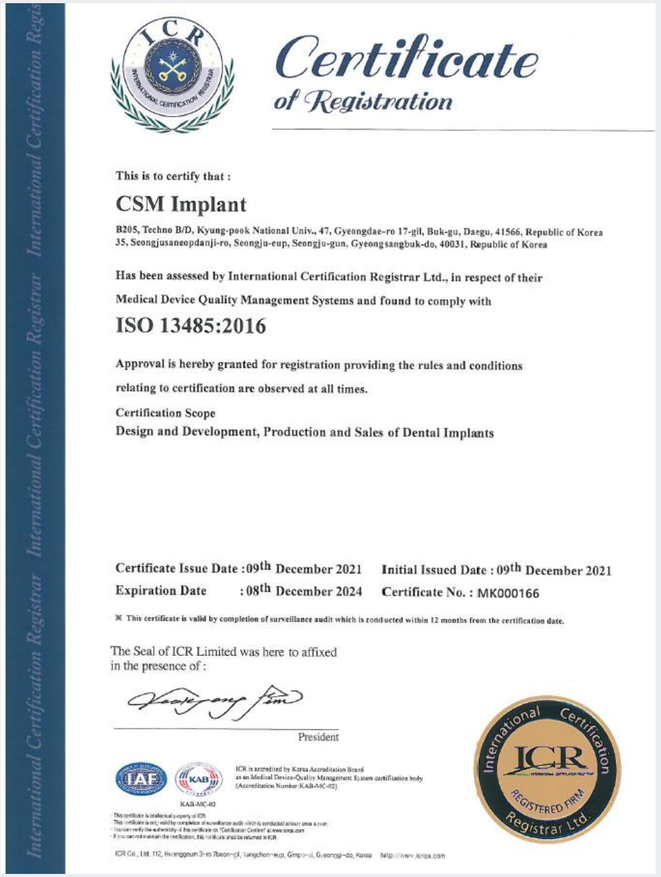
Business Network

1. Current Export Market (21 Countries)
2. Potential Export Market (15 Countries)
3. 2016-2017 New Contract with 5 countries
: Cambodia, Denmark, Spain, Algeria, Jordan

04 Certification & Reference

Certification

ISO 13485



Certificate
of Registration

This is to certify that :

CSM Implant

B205, Techno B/D, Kyung-pook National Univ., 47, Gyeongdae-ro 17-gil, Buk-gu, Daegu, 41566, Republic of Korea
35, Seongjusaneopdanji-ro, Seongju-eup, Seongju-gun, Gyeongsangbuk-do, 40031, Republic of Korea

Has been assessed by International Certification Registrar Ltd., in respect of their
Medical Device Quality Management Systems and found to comply with

ISO 13485:2016

Approval is hereby granted for registration providing the rules and conditions
relating to certification are observed at all times.

Certification Scope
Design and Development, Production and Sales of Dental Implants

Certificate Issue Date : 09th December 2021 Initial Issued Date : 09th December 2021
Expiration Date : 08th December 2024 Certificate No. : MK000166

※ This certificate is valid by completion of surveillance audit which is conducted within 12 months from the certification date.

The Seal of ICR Limited was here to affixed
in the presence of :

President

ICR is accredited by Korea Accreditation Board
as an Medical Device Quality Management System certification body
(Accreditation Number KAB-MC-02)

KAB-MC-02

International Certification Registrar Ltd.

ICR Co., Ltd. 112, Hwanggeum 3-ro 7beon-gil, Jangchon-eup, Gimpo-si, Gyeonggi-do, Korea http://www.icrqa.com

Korea food & Drug Administration

KFDA
Korea Food & Drug Administration
식품의약품안전청

Russia

Taiwan

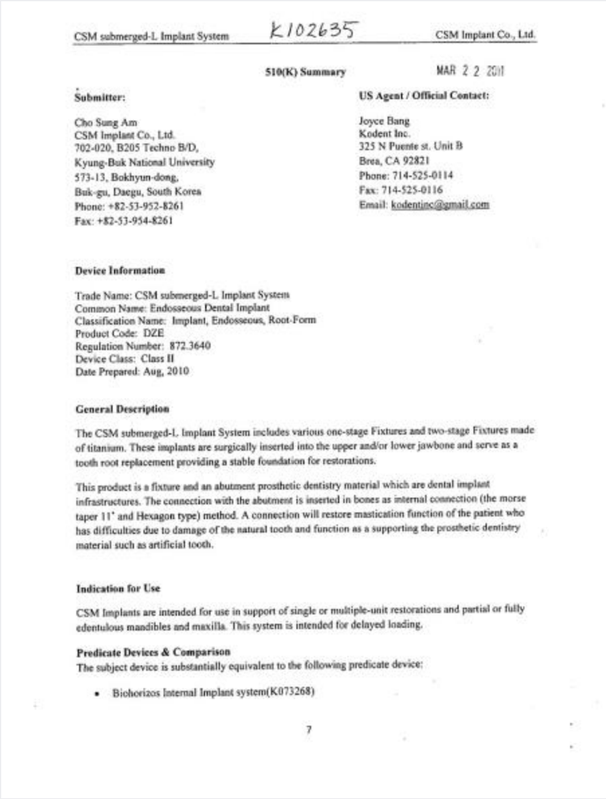
TFDA
Tanzania Food & Drugs Authority

China

CFDA

Certification

FDA of U.S



CSM submerged-L Implant System K102635 CSM Implant Co., Ltd.

510(K) Summary MAR 2 2 2011

Submitter:

Cho Sung Am
CSM Implant Co., Ltd.
702-020, B205 Techno B/D,
Kyung-Buk National University
573-13, Bokhyun-dong,
Buk-gu, Daegu, South Korea
Phone: +82-53-952-8261
Fax: +82-53-954-8261

US Agent / Official Contact:

Joyce Bang
Kodent Inc.
325 N Puente st. Unit B
Brea, CA 92821
Phone: 714-525-0114
Fax: 714-525-0116
Email: kodentinc@gmail.com

Device Information

Trade Name: CSM submerged-L Implant System
Common Name: Endosseous Dental Implant
Classification Name: Implant, Endosseous, Root-Form
Product Code: DZE
Regulation Number: 872.3640
Device Class: Class II
Date Prepared: Aug, 2010

General Description

The CSM submerged-L Implant System includes various one-stage Fixtures and two-stage Fixtures made of titanium. These implants are surgically inserted into the upper and/or lower jawbone and serve as a tooth root replacement providing a stable foundation for restorations.

This product is a fixture and an abutment prosthetic dentistry material which are dental implant infrastructures. The connection with the abutment is inserted in bones as internal connection (the morse taper 11° and Hexagon type) method. A connection will restore mastication function of the patient who has difficulties due to damage of the natural tooth and function as a supporting the prosthetic dentistry material such as artificial tooth.

Indication for Use

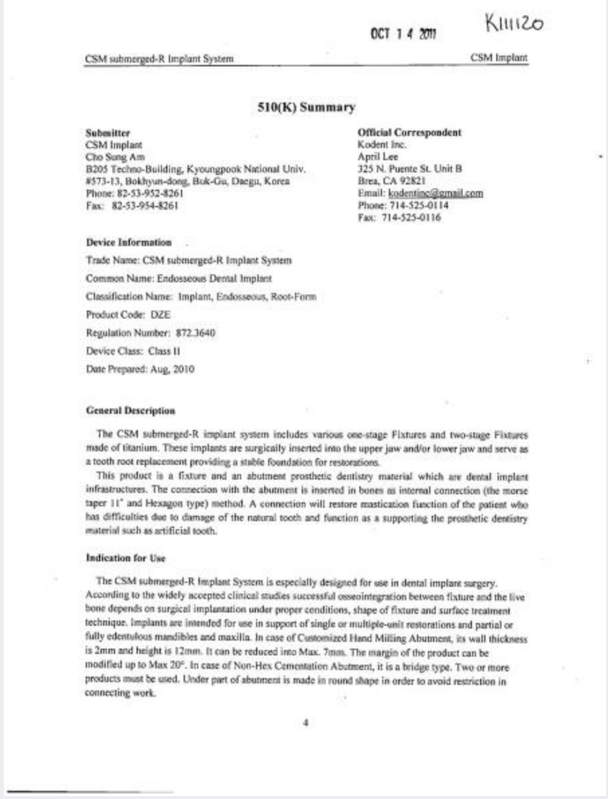
CSM Implants are intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.

Predicate Devices & Comparison

The subject device is substantially equivalent to the following predicate device:

- Biohorizos Internal Implant system(K073268)

7



OCT 1 4 2011 K111120

CSM submerged-R Implant System CSM Implant

510(K) Summary

Submitter
CSM Implant
Cho Sung Am
B205 Techno-Building, Kyoungpook National Univ.
#573-13, Bokhyun-dong, Buk-Gu, Daegu, Korea
Phone: 82-53-952-8261
Fax: 82-53-954-8261

Official Correspondent
Kodent Inc.
April Lee
325 N. Puente St. Unit B
Brea, CA 92821
Email: kodentinc@gmail.com
Phone: 714-525-0114
Fax: 714-525-0116

Device Information

Trade Name: CSM submerged-R Implant System
Common Name: Endosseous Dental Implant
Classification Name: Implant, Endosseous, Root-Form
Product Code: DZE
Regulation Number: 872.3640
Device Class: Class II
Date Prepared: Aug, 2010

General Description

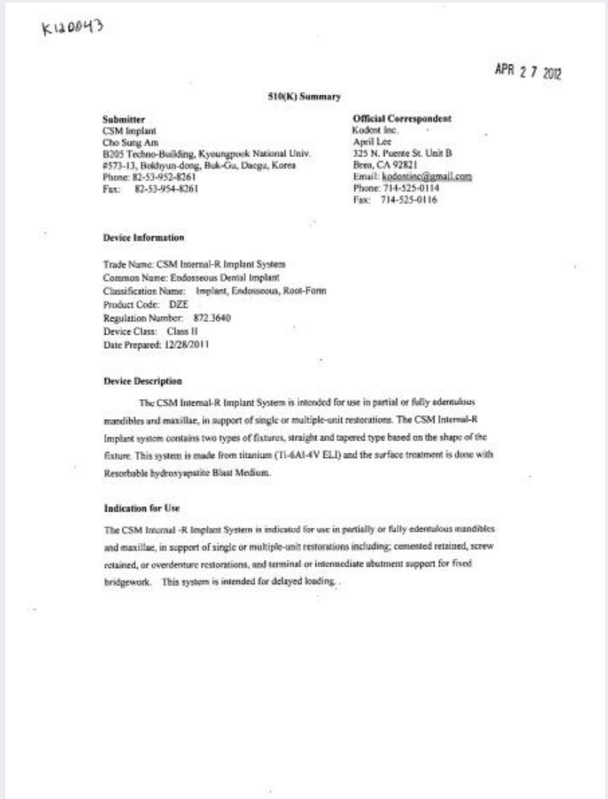
The CSM submerged-R implant system includes various one-stage Fixtures and two-stage Fixtures made of titanium. These implants are surgically inserted into the upper jaw and/or lower jaw and serve as a tooth root replacement providing a stable foundation for restorations.

This product is a fixture and an abutment prosthetic dentistry material which are dental implant infrastructures. The connection with the abutment is inserted in bones as internal connection (the morse taper 11° and Hexagon type) method. A connection will restore mastication function of the patient who has difficulties due to damage of the natural tooth and function as a supporting the prosthetic dentistry material such as artificial tooth.

Indication for Use

The CSM submerged-R Implant System is especially designed for use in dental implant surgery. According to the widely accepted clinical studies successful osseointegration between fixture and the live bone depends on surgical implantation under proper conditions, shape of fixture and surface treatment technique. Implants are intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. In case of Customized Hand Milling Abutment, its wall thickness is 2mm and height is 12mm. It can be reduced into Max. 7mm. The margin of the product can be modified up to Max 20°. In case of Non-Hex Cementation Abutment, it is a bridge type. Two or more products must be used. Under part of abutment is made in round shape in order to avoid restriction in connecting work.

4



K120093

APR 2 7 2012

510(K) Summary

Submitter
CSM Implant
Cho Sung Am
B205 Techno-Building, Kyoungpook National Univ.
#573-13, Bokhyun-dong, Buk-Gu, Daegu, Korea
Phone: 82-53-952-8261
Fax: 82-53-954-8261

Official Correspondent
Kodent Inc.
April Lee
325 N. Puente St. Unit B
Brea, CA 92821
Email: kodentinc@gmail.com
Phone: 714-525-0114
Fax: 714-525-0116

Device Information

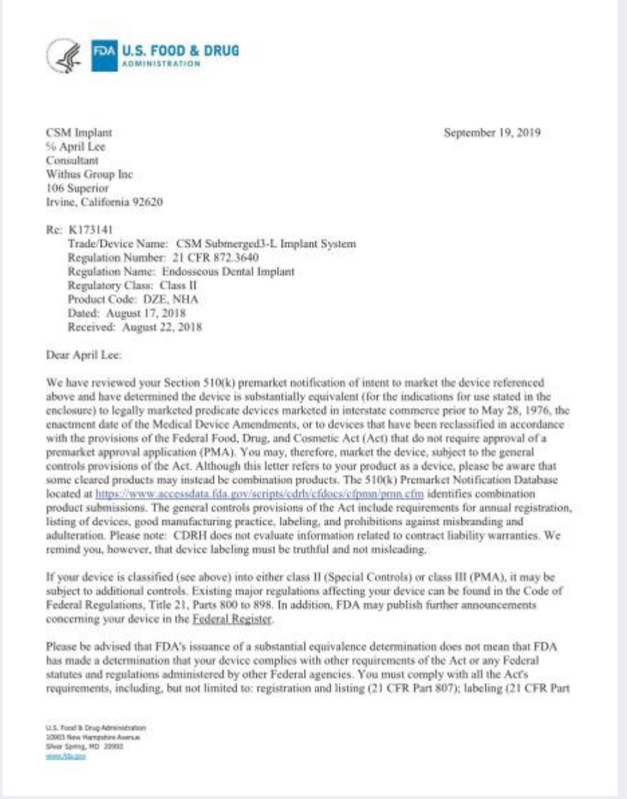
Trade Name: CSM Internal-R Implant System
Common Name: Endosseous Dental Implant
Classification Name: Implant, Endosseous, Root-Form
Product Code: DZE
Regulation Number: 872.3640
Device Class: Class II
Date Prepared: 12/28/2011

Device Description

The CSM Internal-R Implant System is intended for use in partial or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations. The CSM Internal-R Implant system contains two types of fixtures, straight and tapered type based on the shape of the fixture. This system is made from titanium (Ti-6Al-4V ELI) and the surface treatment is done with Resorbable hydroxyapatite Blast Medium.

Indication for Use

The CSM Internal -R Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is intended for delayed loading.



U.S. FOOD & DRUG ADMINISTRATION

CSM Implant
℅ April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

September 19, 2019

Re: K173141
Trade/Device Name: CSM Submerged3-L Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 17, 2018
Received: August 22, 2018

Dear April Lee:

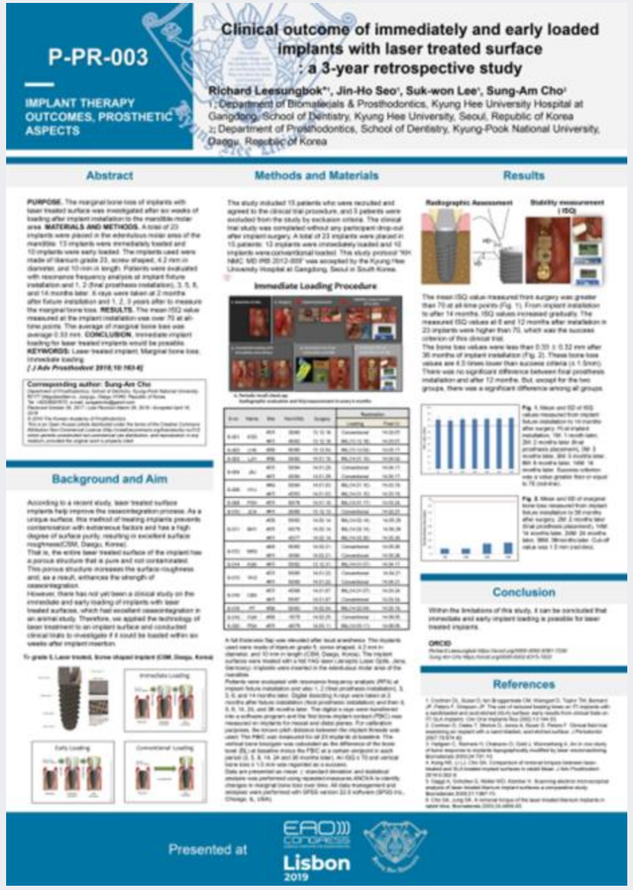
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (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 located 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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

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

Research & Clinical Data



P-PR-003

IMPLANT THERAPY OUTCOMES, PROSTHETIC ASPECTS

Clinical outcome of immediately and early loaded implants with laser treated surface : a 3-year retrospective study

Richard Leesungbok*[1], Jin-Ho Seo[1], Suk-won Lee[1], Sung-Am Cho[2]
1; Department of Biomaterials & Prosthodontics, Kyung Hee University Hospital at Gangdong, School of Dentistry, Kyung Hee University, Seoul, Republic of Korea
2; Department of Prosthodontics, School of Dentistry, Kyung-Pook National University, Daegu, Republic of Korea

Abstract

Methods and Materials

Results

Background and Aim

Conclusion

References

Presented at EAO CONGRESS Lisbon 2019

https://jap.or.kr | J Adv Prosthodont 2018;10:163-6 | https://doi.org/10.4047/jap.2018.10.2.163

Clinical outcome of immediately and early loaded implants with laser treated surface: a 3-year retrospective study

Richard Leesungbok[1], Jin-Ho Seo[1], Sung-Am Cho[2]*
[1]Department of Biomaterials & Prosthodontics, Kyung Hee University Hospital at Gangdong, School of Dentistry, Kyung Hee University, Seoul, Republic of Korea
[2]Department of Prosthodontics, School of Dentistry, Kyung-Pook National University, Daegu, Republic of Korea

PURPOSE. The marginal bone loss of implants with laser treated surface was investigated after six weeks of loading after implant installation to the mandible molar area. **MATERIALS AND METHODS.** A total of 23 implants were placed in the edentulous molar area of the mandible: 13 implants were immediately loaded and 10 implants were early loaded. The implants used were made of titanium grade 23, screw shaped, 4.2 mm in diameter, and 10 mm in length. Patients were evaluated with resonance frequency analysis at implant fixture installation and 1, 2 (final prosthesis installation), 3, 5, 8, and 14 months later. X-rays were taken at 2 months after fixture installation and 1, 2, 3 years after to measure the marginal bone loss. **RESULTS.** The mean ISQ value measured at the implant installation was over 70 at all-time points. The average of marginal bone loss was average 0.33 mm. **CONCLUSION.** Immediate implant loading for laser treated implants would be possible.
[J Adv Prosthodont 2018;10:163-6]

KEYWORDS: Laser treated implant; Marginal bone loss; Immediate loading

INTRODUCTION

The main purposes of implant surface treatment are to increase the surface area to obtain a higher mechanical fixation between bone and implant immediately after insertion,[1] to provide a surface structure that can maintain a blood clot well,[2] and to provide a surface form that can promote the process of bone healing.[3] SLActive technique involves forming surface roughness using large grit with the diameter of 250 - 500 μm after sandblasting and etching by hydrochloric acid and sulfuric acid, then washing in a nitrogen state.[4]

This surface forms a hydroxyl layer and has a high surface energy as a result of contact with water, and increases the ideal contact between the implant and the surrounding factors.[4] The activated surface is preserved and stocked in a physiological saline solution to provide to dental clinics.[5] The chlorine ions, as anions, and hydroxyl ions are combined to protect the activated surface from air and prevent hydrocarbon binding.[5,6] Based on previous studies, it had been found that these surface properties significantly increased bone to implant contact and resulted in an accelerated healing process of osseointegration during the early stage. This effect leads to enhanced stability of the implant and aids in healing during the critical early stages.[5,11]

According to a recent study, laser treated surface implants help improve the osseointegration process.[12] As a unique surface, this method of treating implants prevents contamination with extraneous factors and has a high degree of surface purity, resulting in excellent surface roughness. That is, the entire laser treated surface of the implant has a porous structure that is pure and not contaminated. This porous structure increases the surface roughness and, as a result,

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Received October 28, 2017 / Last Revision March 29, 2018 / Accepted April 16, 2018

This research was supported by Small and medium business administration (SMBA) and Korea medical devices industrial coop. association (KMDICA) in the Korean Government Fund.

J Korean Acad Prosthodont : Volume 45, Number 3, 2007

RETROSPECTIVE MULTICENTER STUDY OF CSM ENDOSSEOUS DENTAL IMPLANT

Eun-Young Park, D.D.S., M.S.D.
Department of Dentistry, College of Medicine, Youngnam University

Statement of problem. To work the economic limitation of dental implant usage, some types of domestic implant have been developing. But, there have been seldom reported about the clinical success rate of them as yet.

Purpose. The aim of this retrospective multicenter study was to evaluate the performance of CSM implants(CSM company, Daegu, Korea).

Material and methods. Thirty-five patients were rehabilitated with 150 CSM implants in this multicenter study.

Results. The success rate was 96.2%. CSM Titanium fixtures can obtain slightly higher success rate when a cover screw was not used for implant installation than when used. However it doesn`t show significant difference($p=.7615$, Fisher`s Exact test).

Conclusion. This multicenter retrospective study demonstrated the efficacy of the CSM implant in the treatment of variety of clinical manifestation of tooth loss. And it can be assumed that whether a cover screw is used or not should no influence on the osseointegration.

Key Words
CSM implants, Cover screws, Success rate

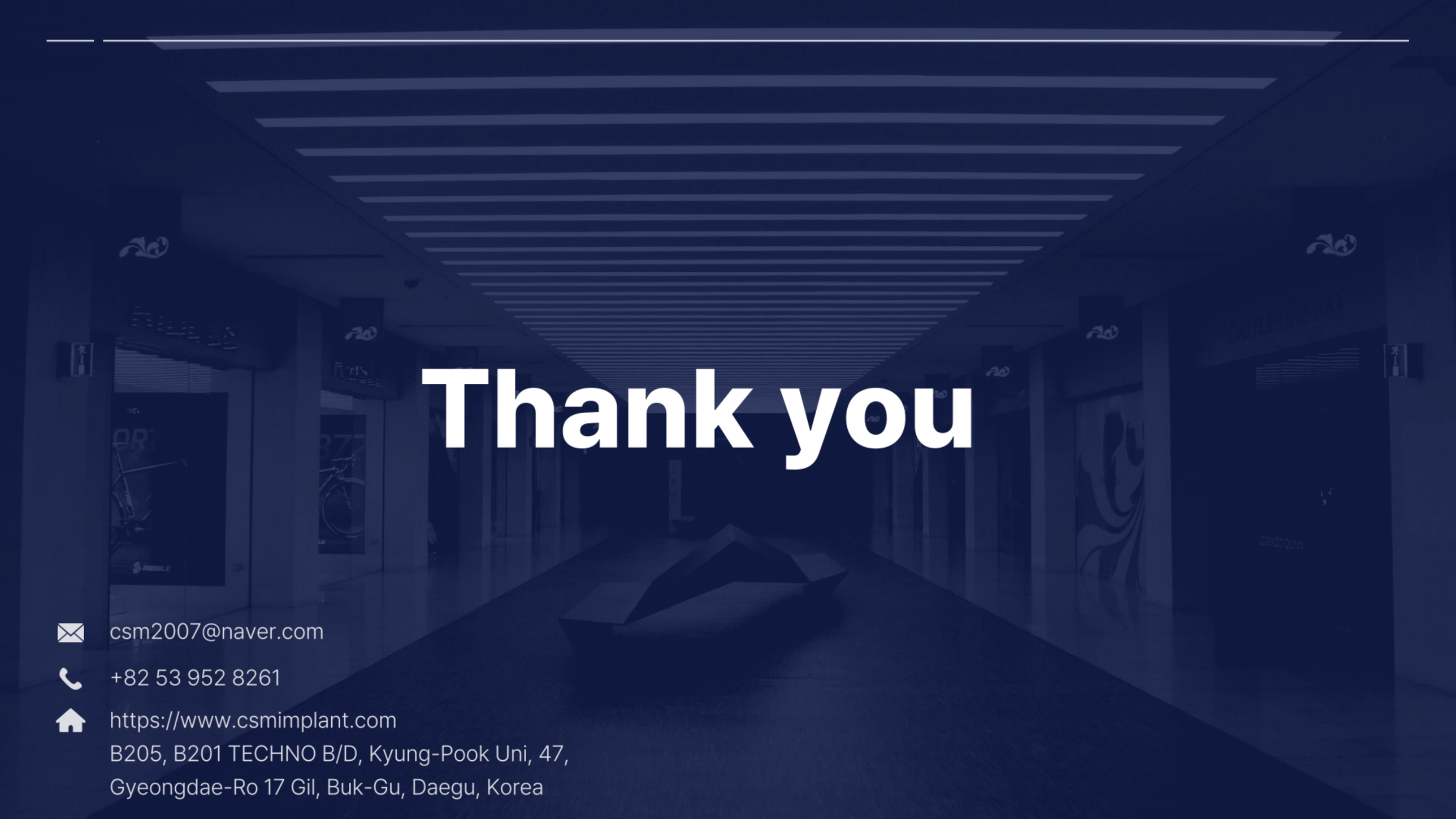
Although most denture-wearing patients appear to adapt to wearing their prostheses, a significant number do not.[1] The introduction of osseointegrated implant for replacement of missing or lost dentition by Brånemark et al. has revolutionized restorative dentistry.[2] After the Toronto Conference, universally began used endosseous implants for the restoration of edentulous patients.[3] Initially, the concept of osseointegration was only proposed for the treatment of edentulous patients[27] However favorable extended prognosis for osseointegrated titanium implants in edentulous patients[2] has led to expanding application in partial edentulism. Furthermore, in the replacement of missing single teeth, it has become an accepted form of treatment.[4-6]

But, within the country, implants have not been popularized as yet. A fear of the implant surgery should partially account for that, but the greatest reason seems to be a expensive fee due to the high price of implant materials which entirely have depend on an income.

Recently, in order to work this problem, some types of domestic implant have been developing and the interest about them has increased. Nevertheless most of dentists are anxious about the use of domestic implants, because there have

05 Video

Video



Thank you

csm2007@naver.com

+82 53 952 8261

https://www.csmimplant.com

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Gyeongdae-Ro 17 Gil, Buk-Gu, Daegu, Korea