

Surface treatment technology of low-temperature plasma for implant surface super hydrophilization to improve osseointegration of dental implants

● Presenter : Jeong, Gab Moon



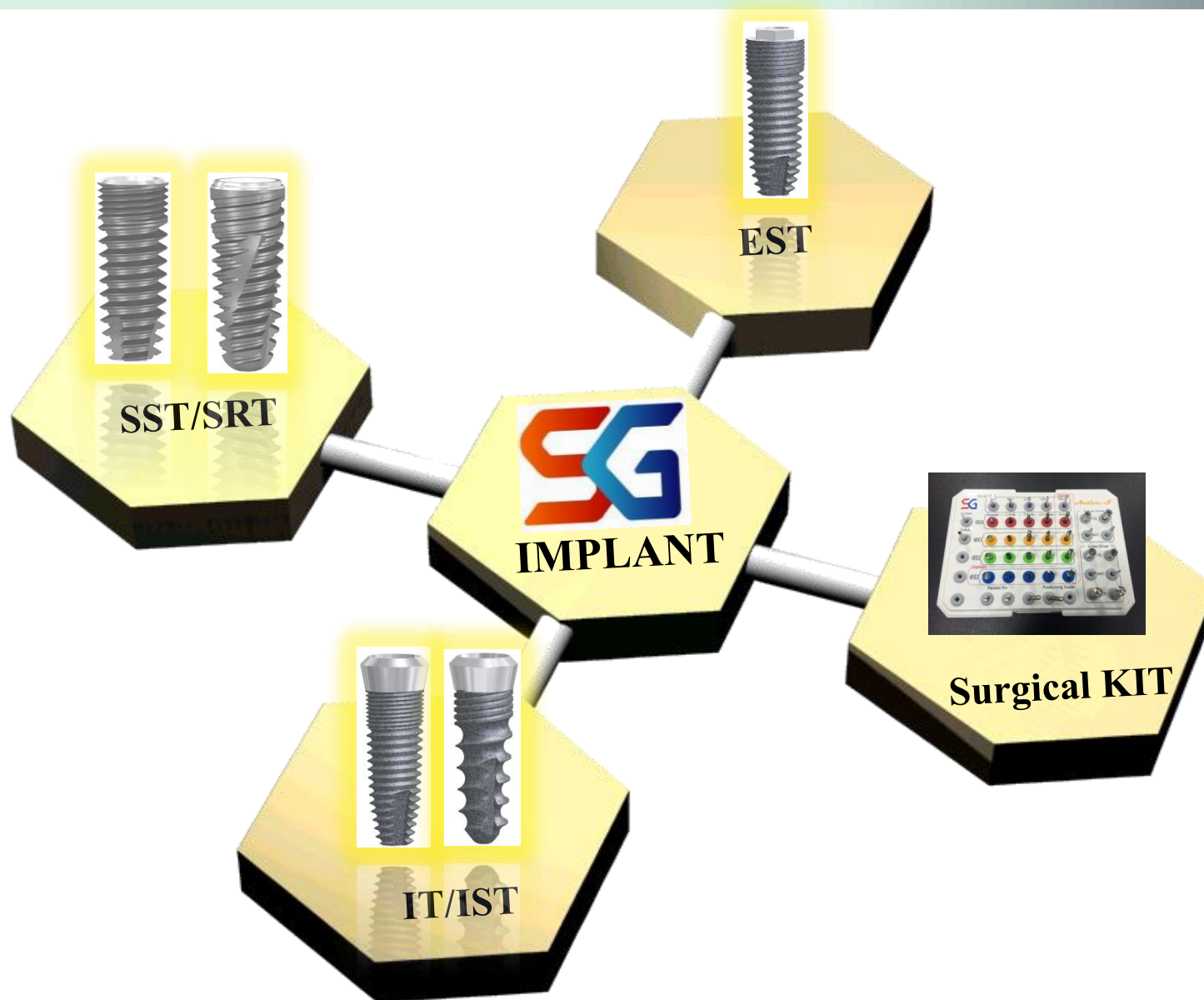
Company Profile

Name of Company		ShinSaeGi Medi-Tech Co., Ltd.	Date of Business Commencement	December. 13. 2007	
Name of President		Seung Kwan Paik	Business registration number	606-86-06956	
Address	Head office	#501, Gimhae Biomedical center, 80-59, Goldroot-ro, Juchon-myeon, Gimhae-si, Gyeongsangnam-do, Korea			
	Factory	#102, Gimhae Biomedical center, 80-59, Goldroot-ro, Juchon-myeon, Gimhae-si, Gyeongsangnam-do, Korea			
Tel		+82-55-338-2815	Staff in Charge	Name	Gab Moon Jeong
Fax		+82-55-338-2818		Tel	070-8897-8802
Home Page		www.sgimplant.com	E-mail	sgimplant@sgimplant.com	
Business Type		Manufacturing	Business Item	Manufacture of Dental Instruments and Appliances	

History

2007	Establishment
2008	<ul style="list-style-type: none"> •CAD/CAM Development •KFDA Certificate Acquisition (Class I)
2009	<ul style="list-style-type: none"> •KDA Certificate Acquisition (Class III) •CFDA Certificate Acquisition (Class I) •ISO13485 & CE certification Acquisition
2011	Shanghai branch establishment (KOTRA)
2012	CFDA Certificate Acquisition (Class III)
2013	Overseas sales start(Besides China)
2014	Components and Materials Institute Establishment
2015	<ul style="list-style-type: none"> •Quality Fitness Certification by KFDA (GMP) •Head Office Relocation (Gimhae Biomedical Center)
2016	CFDA Certificate Re-Acquisition (Class III : 2016.03.31~2021.03.30)
2017	<ul style="list-style-type: none"> •Establishment of company-affiliated technology research institute •Promising Export firm by the small and medium business administration, Republic of Korea
2018	<ul style="list-style-type: none"> •CEO Seung-Kwan Paik of SHINSAEGI Medi-Tech received the Grand Prize in the 2018 Korea Innovation Medical Industry category. •Acquired 2 patents

SG Implant System



Project summary

Project Title Surface treatment technology of low-temperature plasma for implant surface super hydrophilization to improve osseointegration of dental implants

Main organization ShinSaeGi Medi-Tech (Gimhae, Kyungnam)
Main Products : Dental Implant



Voucher Service Agency Korea Institute of Materials Science (Changwon, Kyungnam)
Support content :
Development of low temperature plasma generator and development of surface treatment process



R&D Technology summary

1 Dental Implant: Fixture



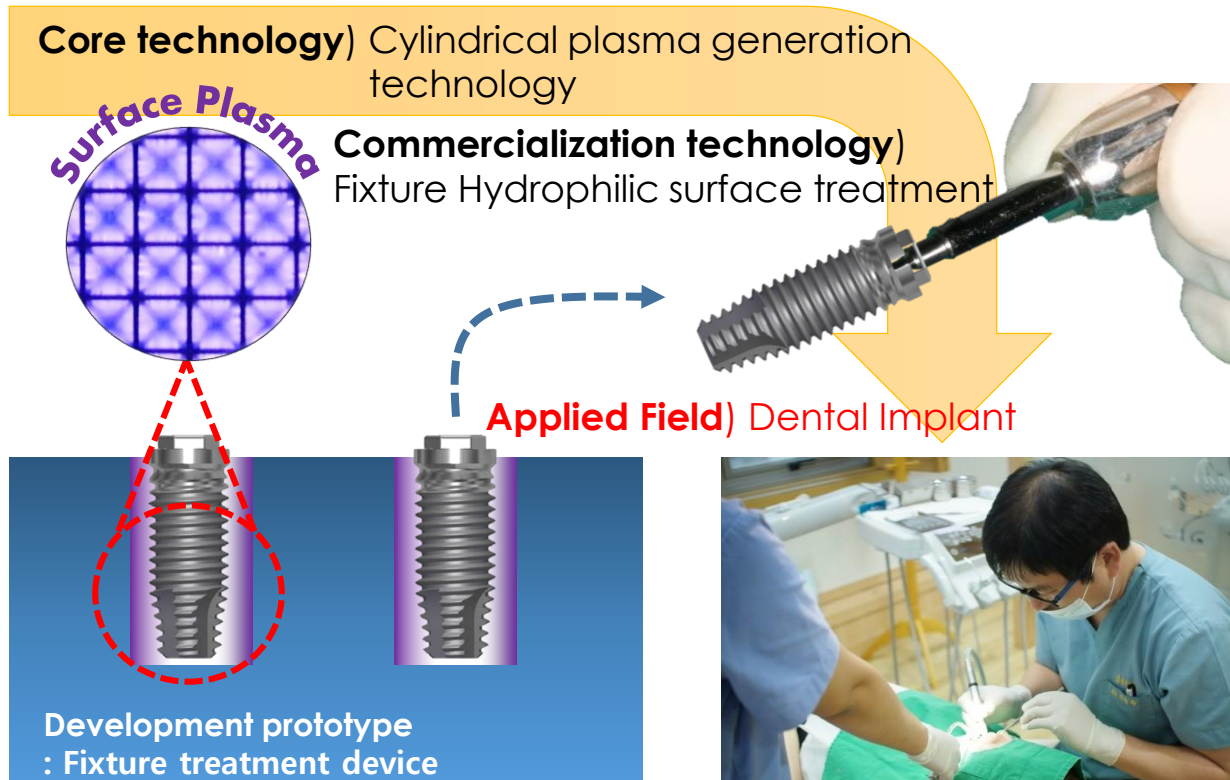
Artificial teeth used to restore the patient's masticatory function

R&D Technology summary

2 Cylindrical Plasma Generator Application Dental Implant Fixture Hydrophilization Technology

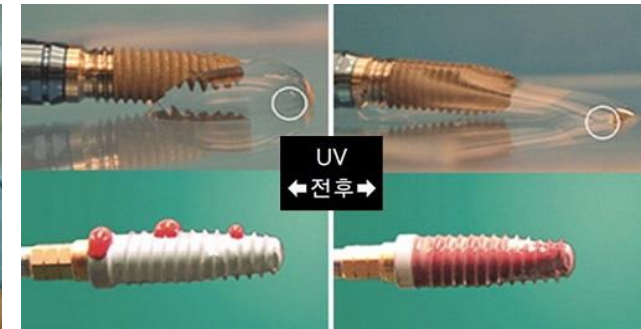
Core Technology: Low-temperature plasma surface treatment technology for short-time (within 1 minute) 3-D surface hydrophilization of dental implants

Expected effect: Improvement of bone adhesion success rate of 50% to 90% through hydrophilic treatment ¹⁾



Plasma application Hydrophilic surface treatment: Increase hydrophilicity to attract blood and protein to induce rapid osseointegration.

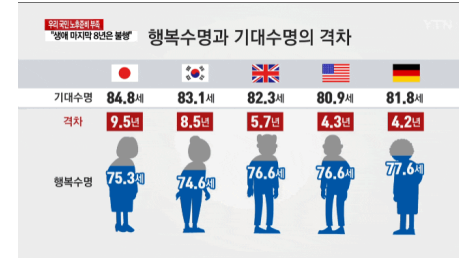
¹⁾The Kyunghyang Shinmun (2017.08.21)



R&D Necessity: contributes to prolonging health life

1 Efforts to reduce the difference between life expectancy and life expectancy

2030 Life expectancy 90 years old



Life expectancy increases, but for a healthy life of old age?
=> Need for social welfare for the elderly/health

2 It is possible to maintain healthy teeth in old age through implants → Implant market continues to grow!

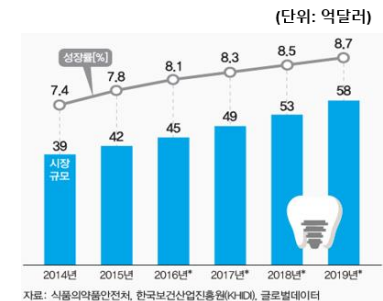
Need to secure dental health for old age



Before

After

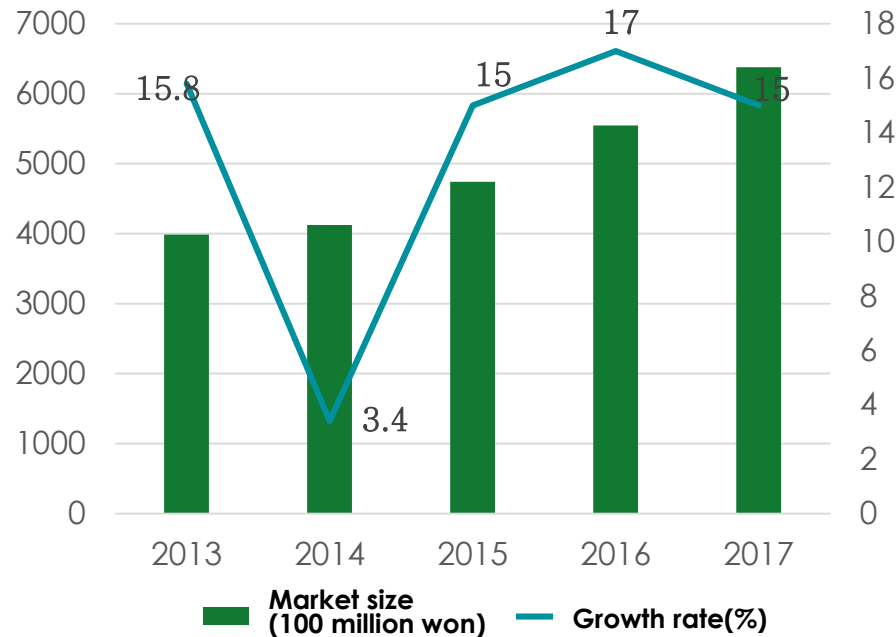
Dental Implants: Recovery of Health and Confidence



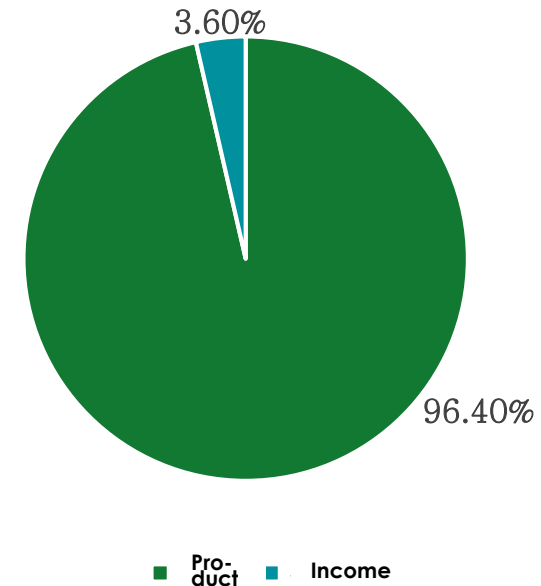
Dental Implant Market

Domestic Implant Market Forecast

1/ Growth of more than 15% a year; but expected to enter a low growth phase soon



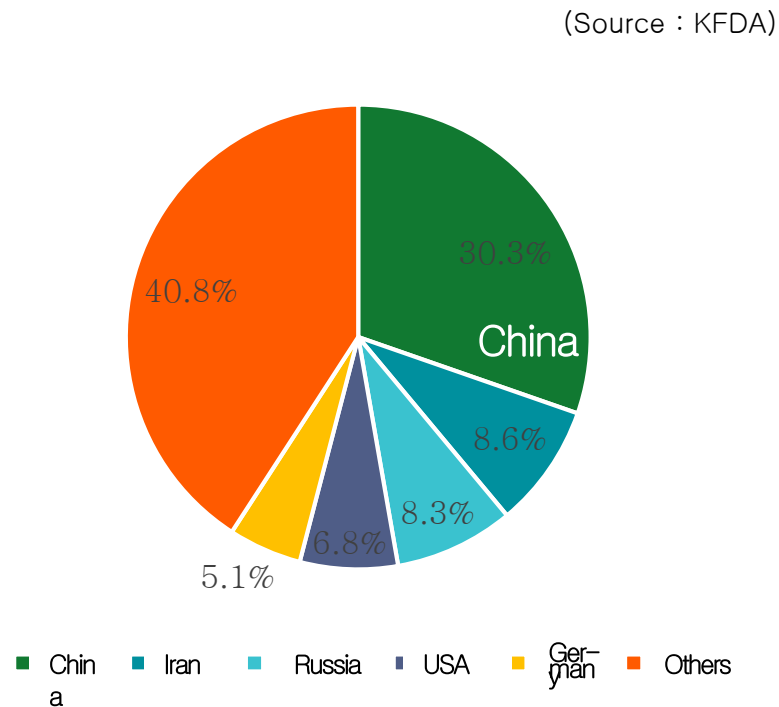
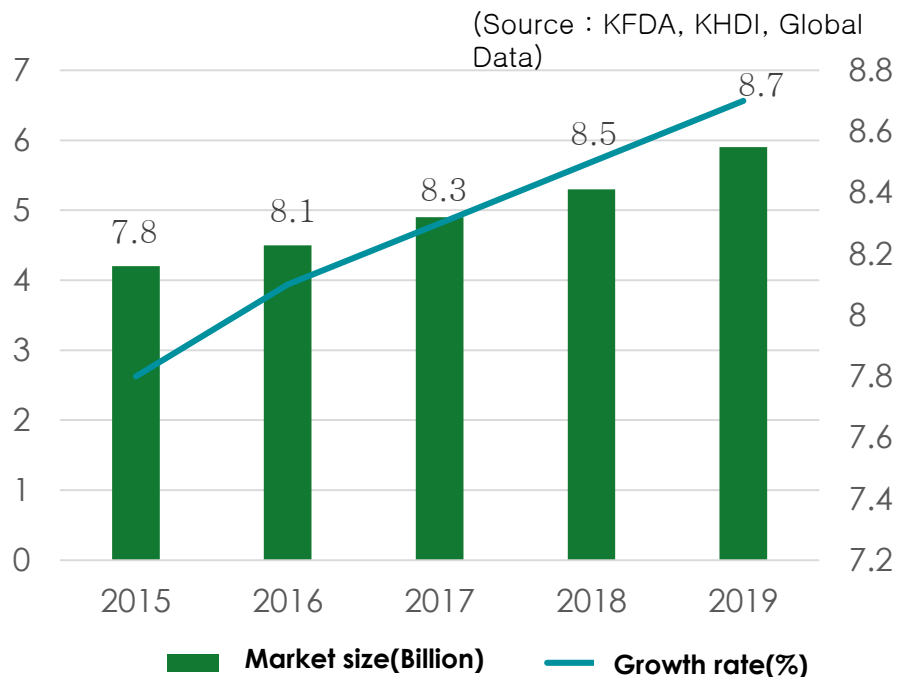
(Source : KFDA, KHDI, Global Data)



- **Currently** : Domestic dental implants have grown at a CAGR of 15% over the past five years
- **Outlook** : Domestic products will be dominant and expected to grow by 4% over the next five years (52 companies including Dio, Osstem and Dentium)
- **Dental implants needed for high performance (to improve procedure success rate) to secure growth engines in the domestic market!**

Overseas Implant Market Forecast

1 Continuing Growth (Blue Ocean China)



- The overseas dental implant market is growing at a CAGR of more than 8%
- **Currently:** Exporting domestic products to 99 countries including China and Iran
- **High functionality (to improve the procedure success rate) Implants Product Strategy is required Market: China (Domestic product exports: 30.3%)**

Development Status of High Functional Implant Technology

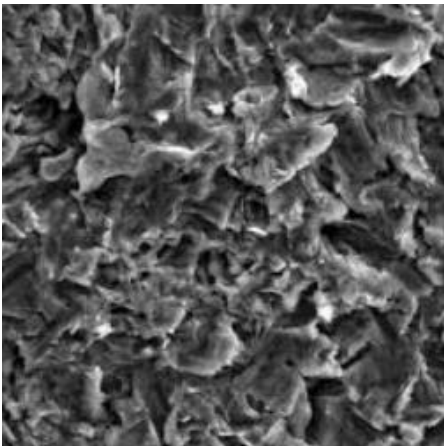
1 Core Technology : Implant lipidation and osseointegration promotion technology through plasma irradiation

Various surface treatment research and development to increase implant success rate

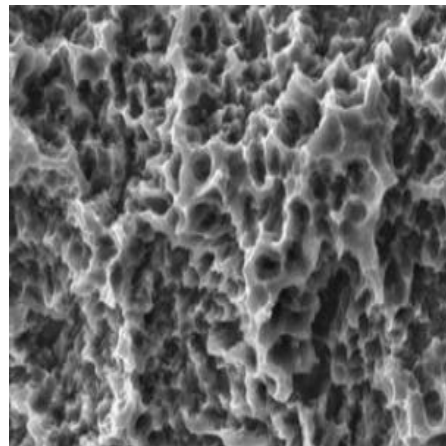
: The initial machined surface has long term data and its success rate is not bad.

① Bad bone quality ② Bone graft is needed ③ Immediate load is required

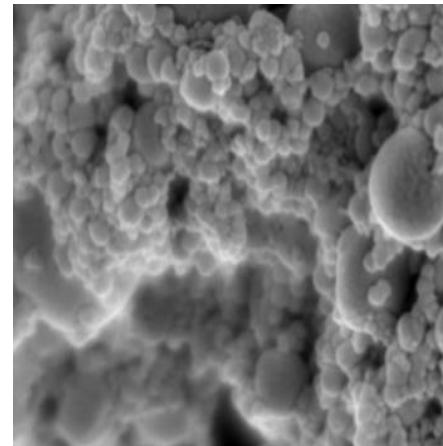
=> Rough surface is needed to induce faster osseointegration and success



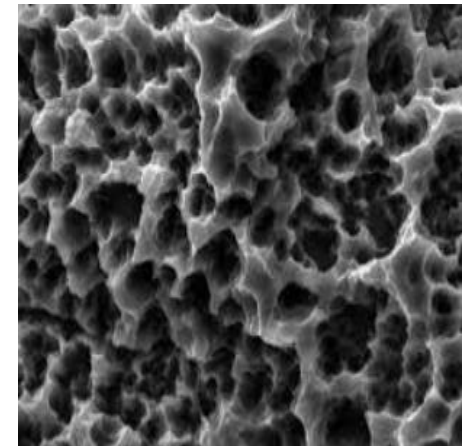
RB M



SLA



HA Coating



SLA Active : **Store in Physiological saline**

Development Status of High Functional Implant Technology

2 Core Technology : Implant lipidation and osseointegration promotion technology through plasma irradiation

Current Dental Implant Problems

- As the time elapsed after the final surface treatment (about 1 month), the implant is adsorbed with organic impurities on the surface of the titanium implant to inhibit the early osteosynthesis due to biological aging

Solutions

- Photofunctionalization imparts hydrophilicity to the hydrophobized titanium surface by photocatalytic action.
- As the organic impurities are removed, the surface of the hydrophilicized implant titanium induces attachment, spreading, proliferation and differentiation of osteoblasts, inducing protein adsorption

Aging phenomena

Organic matter is formed on the surface of the implant due to air contact, resulting in biological aging which interferes with osseointegration.

Air contact

∨

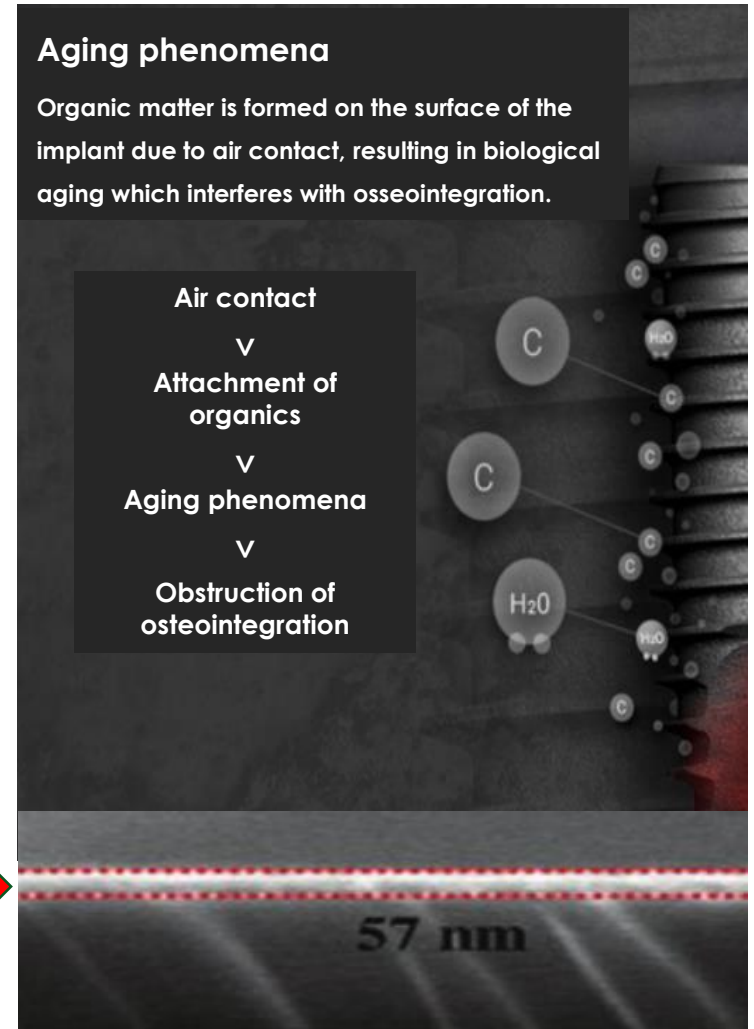
Attachment of organics

∨

Aging phenomena

∨


Obstruction of osseointegration



Development Status of High Functional Implant Technology

3 Current technology level : Improved procedure success rate through ultraviolet lamp application surface treatment

SLA에 UV를 더하다!
세계 최초 밀폐형 광촉매 UV 처리기술



Why Ultraviolet Implants?

임플란트는 생산된 뒤 4주가 지나면 질에 녹이 스는 것처럼 변화가 생깁니다. 자외선임플란트는 임플란트 노화의 주 원인인 탄화수소 침착을 제거하여 기존에 50~60%에 불과하던 골융합 성공률을 90% 수준까지 높여줍니다.

01

잇몸뼈가 약하고
신체활성이
떨어지는 노인분

02

당뇨, 고혈압 등
전신질환에
합병증이
두려우신분

03

받지아지마자
바로 임플란트를
식입해야 하는분


See Figure: Point Implant

UV IMPLANT POINT 01

Excellent blood absorption

General Implant


(물방울이 스며들지 않고 맺힘)



시술기간: 3~4개월

UV Implant

(물방울이 즉시 흡수됨)



시술기간: 1~2개월

Vs

기존 임플란트는 시간의 경과에 따라 표면에 유기물이 부착되어 생물학적 노화현상이 일어나지만 UV 광선을 조사하는 자외선 임플란트는 표면의 탄화수소 등이 CO2와 H2O의 형태로 발생되어 깨끗한 표면으로 바뀌고, 아러디칼 반응에 의해 초친수성을 띠게 됩니다.

- Principle
 - Ultraviolet lamps produce UV rays, ozone and OH active species.
 - Ultraviolet: decomposition of organic matter.
 - Oxygen activations (Ozone, OH): Decomposition of organic matter.
- Weakness
 - Long irradiation time (more than 20 minutes)
 - Difficult to respond immediately to changes in

Item	UV-rays	Plasma
Commercially available products	domestic 3 / Overseas 2	domestic 1 (Shinsaegi)
Irradiation time	20 min ~	15 ~ 20 sec
Expendables	UV Lamp	O ₃ Filter
Price	₩10,000,000 ~ 15,000,000	₩ 5,000,000 ~ 7,000,000

Advantages

- ① Short irradiation time
- ② Uniform irradiation on the surface
- ③ Low price

Development Status of High Functional Implant Technology

4 Onsite demand increased demand for implant hydrophilic devices in a short period of time

User (Dentist) Requirement

- Irradiation time in 1 minute
- Easy to use

Plasma technology application

Technical requirements

- 1 ppm of ozone and ultraviolet radiation can be generated at the same time.
- Low-temperature plasma devices applicable to implant structures
- High-voltage durability of plasma generation devices

5 Benefit : Expansion of sales target due to enlargement of procedures and improvement of procedure success rate

- Sterilization effect of implant surface
- Promote early bone formation
- Minimize complications
- Shortening healing time

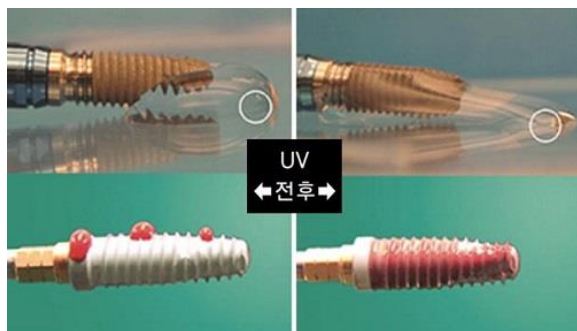
High surgical success rate

Expansion of surgery for systemic diseases and old patients

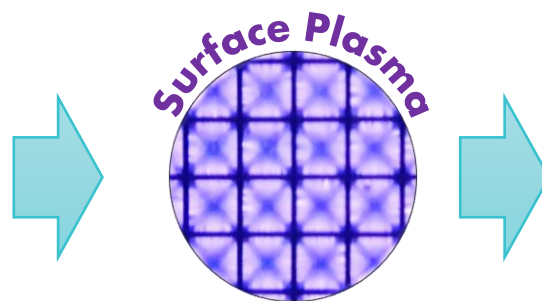
Prior cooperation contents

1 Transfer of low-temperature plasma technology to Shinsaegi MedTech (27 billion)

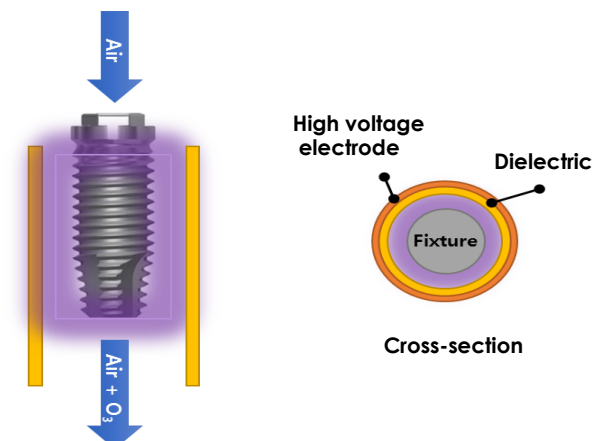
- Demand technique : Dental implant surface treatment technology with shorter irradiation time and better hydration performance than traditional UV devices
- Korea Institute of Materials Science holding technique : Surface Plasma Generating Material and Generator Design Technique for 3-Dimensional Surface Processing
- Development Technology : Development of Low-temperature plasma treatment device for hydration of implants surface using Surface Plasma



Improvement of general implant with 50 % success rate of bone adhesion to 90% by ultraviolet water treatment
Source: Kyunghyang Shinmun (2017.08.21)



Korea Institute of Materials Science holding technique
Low-temperature plasma generation technology



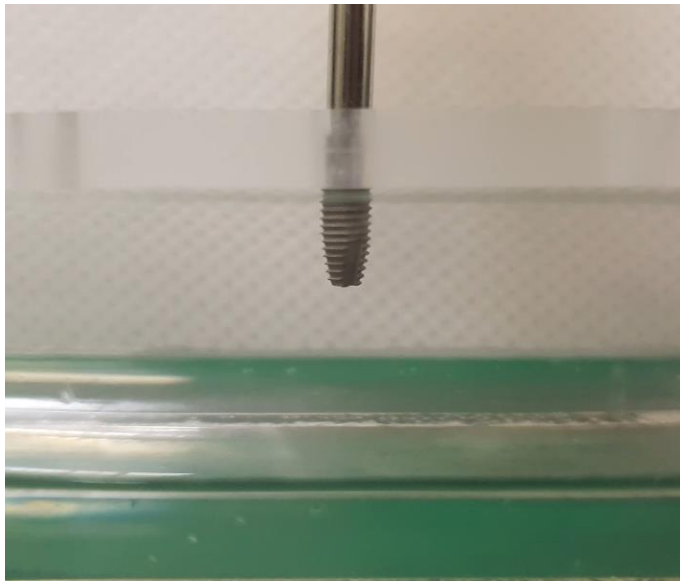
Conceptual diagram

Development of low-temperature plasma application implant surface treatment device

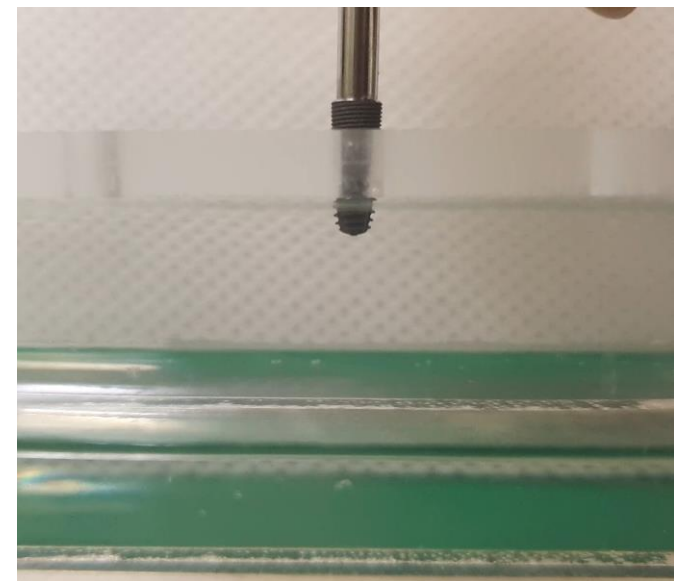
Confirm superior hydrophilization performance compared to existing technology

1 Confirmation of implant hydrophilization through plasma surface treatment process (processing time: within 1 minute)

- Two kinds of main products of Shinsaegi Medi-Tech can be hydrophilized by low-temperature plasma surface treatment
- Improved convenience for the dentist by implementing the processing time of less than 1 minute which is impossible in the existing ultraviolet ray process
(Visit of the dental director of Changwon Nae-Dong dental clinic, confirmation of actual user's opinion through demonstration of hydrophilic performance)



SLA



RBM

Confirm superior hydrophilization performance compared to existing technology

2 Special broadcast of KBS Changwon(2019. 3)

Institute's original technology, Enable manufacturer 'Virtuous cycle'

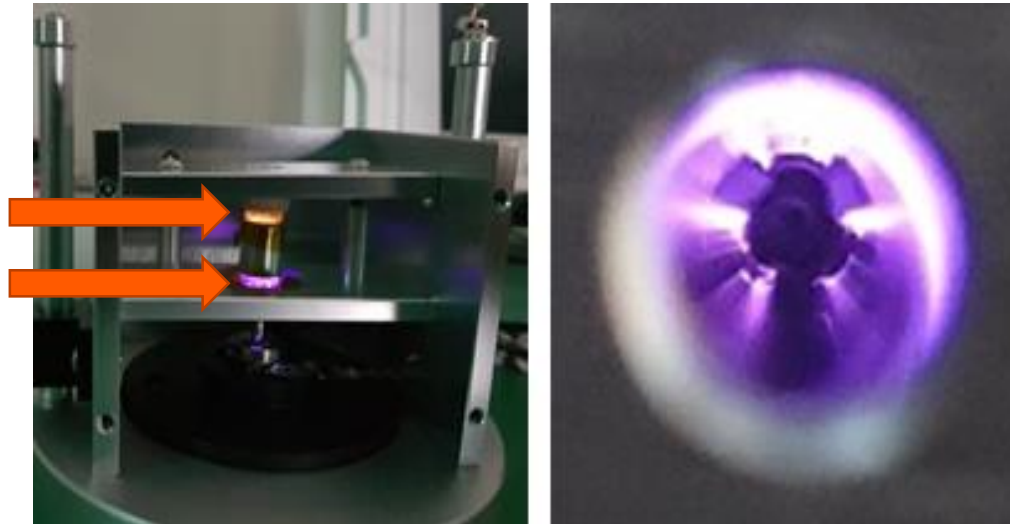


Difficulties in developing new products

1 Design for user convenience and development of product to secure high voltage stability

- Design of a low-temperature plasma surface treatment device that is easy to use by a physician in dentistry
 - Design of electric safety improvement considering high voltage insulation breakdown durability
- => Design evaluation of prototype product considering user convenience and electrical safety at the same time

Insulation destruction
damage area



Final goals and development content

1 **Final goal** : Development of a lowtemperature plasma surface treatment device for dental implant fixture hydrophilicization

- Development of Cylindrical Air Plasma Generating Device for Hydrophilic Surface Treatment of Implant Fixture Products of Shinsaegi Medi-Tech Co., Ltd.
- Development of prototype application process through evaluation of implant fixture hydrophilicity (time, hydrophilicity) of development equipment
- Manufacture of prototype surface treatment of implant with optimized implantation process

Shinsaegi Medi-Tech

- Prototype design consisting of plasma generator, implant insert, ozone removal device, etc.
- Assembling parts for prototype production
- Development of equipment operation process

Korea Institute of Materials Science

- Development of high voltage safety technology for plasma generator
- Design and experimental demonstration of dielectric structure based on computer simulation
- Design and manufacture of plasma generator

Performance Indicator Objectives

1 Set processing time, hydrophilization performance, high voltage stability as major technical performance indicators

< Key Performance Indicators Overview >				
Key performance indicators	unit	Final development goal	Pre-development level	Assessment Methods
Processing time	sec	60 Below	1200 More than	Carry out witness test evaluation after self-evaluation
Implant Hydrophilic	mm/sec	1 More than	1 Below	Carry out witness test evaluation after self-evaluation
High voltage durability	kV	5 More than	none	External agency commission none
<p>※ Reason for establishing self-measurement index</p> <ul style="list-style-type: none"> ◦ Processing time: Issuance of the official report of the relevant indicator, evaluation is conducted by invitation of relevant experts because there is no official testing institute. ◦ Implant wettability: The general water contact angle evaluation is difficult to apply to the screw-shaped implant surface, and the wetting property of the implant is set as the main performance index and evaluation is carried out in the presence of invited experts 				

Thank you.