C-SLA

Clean-SLA Surface
with Clean-Tech™

DENTIS


Ultra-Pure, Ultra-Safe
Clean-SLA Surface with Clean-Tech™
C-SLA™
DENTIS

ORIGIN

CLEAN first,
second and third

Starts with

SLA

(Straumman)

Ends with

C-SLA™

(DENTIS)

1997

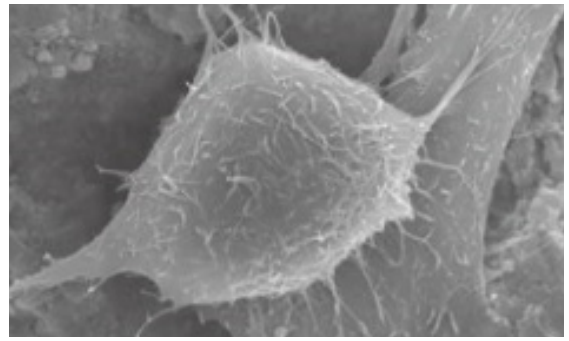
SLA
(Straumman)

- Developed the industry's first SLA surface treatment
- Proven long-term stability through multiple clinical cases
- Currently, the standard for implant surface treatment

2012

C-SLA™
(DENTIS)

- C-SLA™ completed with Clean-Tech™ by DENTIS Smart Clean Factory'



Global Standard
Surface Treatment
S·L·A

In 1997, SLA Surface Technology was pioneered by the Swiss medical device manufacturing company 'Straumann.'

Renowned for its proven safety in extensive clinical cases, SLA surface technology stands as the most extensively utilized surface technology worldwide.

Fig. 1

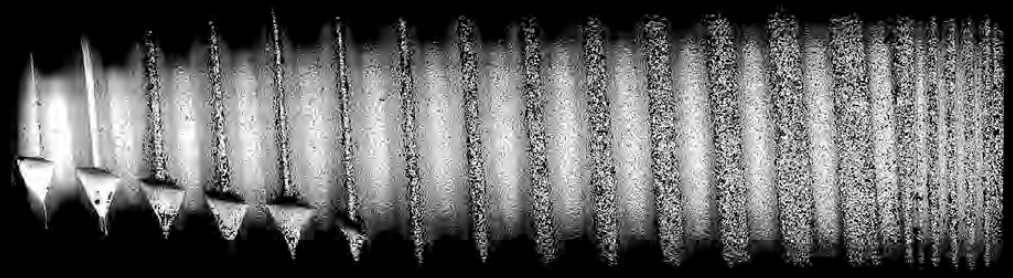


Fig. 2

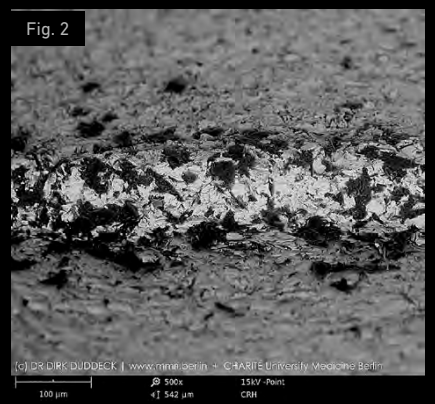


Fig. 1: Massive organic pollution on sterile packaged implant (SEM mapping at 500x).

Fig. 2: Organic particles on the implant thread (SEM image at 500x).

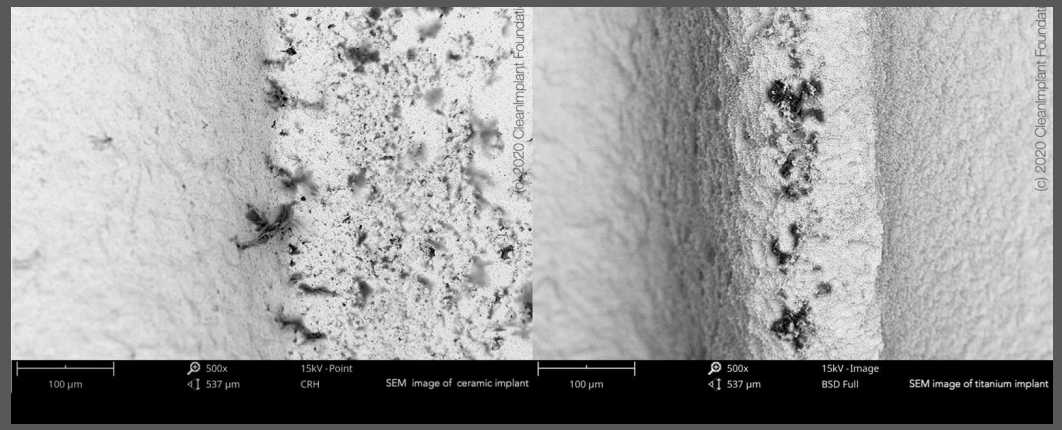
Fig. 3: Organic particles with antimony on the implant shoulder (SEM image at 500x).

*[Clean Implant] Quality seal for dental implants- More safety for patients and practitioners (by Dr. Dirk U. Duddeck)

Quality deficiencies of sterile-packaged ceramic and titanium implants

Article by Dr. Dirk U. Duddeck, published in: Dental Tribune U.S. 4-2020

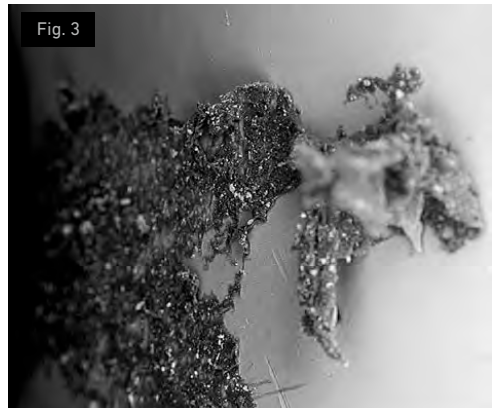
In 2019, the FDA released two decades of previously unpublished data and 2.1 million reports of failed dental implants from which more than 100,000 reports referred to 2018 alone. Most of these failures related to a lack of osseointegration, raising major concerns among dentists in the US and abroad as the number of additional unreported losses is likely to be much higher. Comments made by manufacturers, regarding these figures, focus on patients with unfavorable clinical preconditions and even blame dentists for their lack of experience and training.



Is this the whole truth?

In a recent study, conducted by the non-profit CleanImplant Foundation in collaboration with the Charitè University Berlin, more than 100 different sterile-packaged implants - including ceramic and titanium implants - from 80 implant brands were analyzed. SEM imaging and elemental analysis (EDS) were performed in an officially accredited testing laboratory, according to DIN EN ISO/IEC 17025. Almost every second implant sample that was unpacked under cleanroom conditions and analyzed in the SEM showed considerable contamination, i.e. unwanted particles originating from the manufacturing, handling or packaging of the implant. These contaminants on sterile packaged implants, especially organic particles from the manufacturing or packaging process, can cause an uncontrolled foreign body reaction resulting in osteoclastogenesis, leaving rough areas of the implant surface exposed to bacterial colonization

Fig. 3



Implant fail

Aluminum oxide (Al203) and

blasting residues on the SLA surface..

Is acid treatment **Safe?**

Is my implant **Fine?**

Ultra-Pure, Ultra-Safe
Clean-SLA Surface with Clean-Tech™

DENTIS

C-SLA™

Clean - SLA Surface
with Clean - Tech™

SLA,
Becomes
C-SLA™

DENTIS has innovatively applied Clean-Tech™ to the globally recognized SLA surface, resulting in the development of CLEAN SLA, abbreviated as C-SLA™ surface technology.

"Through DENTIS' unique Clean-Tech™, concerns regarding 'residue' and 'toxicity', typically associated with the traditional SLA surface treatment processes involving Sandblasting, Large Grit, and Acid Etching, have been eliminated. This advancement has significantly enhanced the clinical safety standards.

As a result of these endeavors, 'C-SLA™' has achieved an unprecedented outcome with 0% residue and 0% lot defects."

01

Clean First

Inheriting DENTIS' 'Clean Spirit' that started in 2006,

we focus on 'CLEAN' with the

mindset of placing our implant in our family. Clean comes first for the first,

second, and third in our minds.

02

Ultra Pure Ultra Safe

We aim for 'purity' beyond cleanliness.

Equipped with ultra-pure water and ultra-precision cleaning

*sterilization facilities and we have established an independent clean process system.

Through rigorous quality control and production, we manufacture even more reliable implants.

03

Advanced Technology

Through cutting-edge equipment such as the Vacuum Cleaning Machine,

automated cleaning processes, automated packaging,

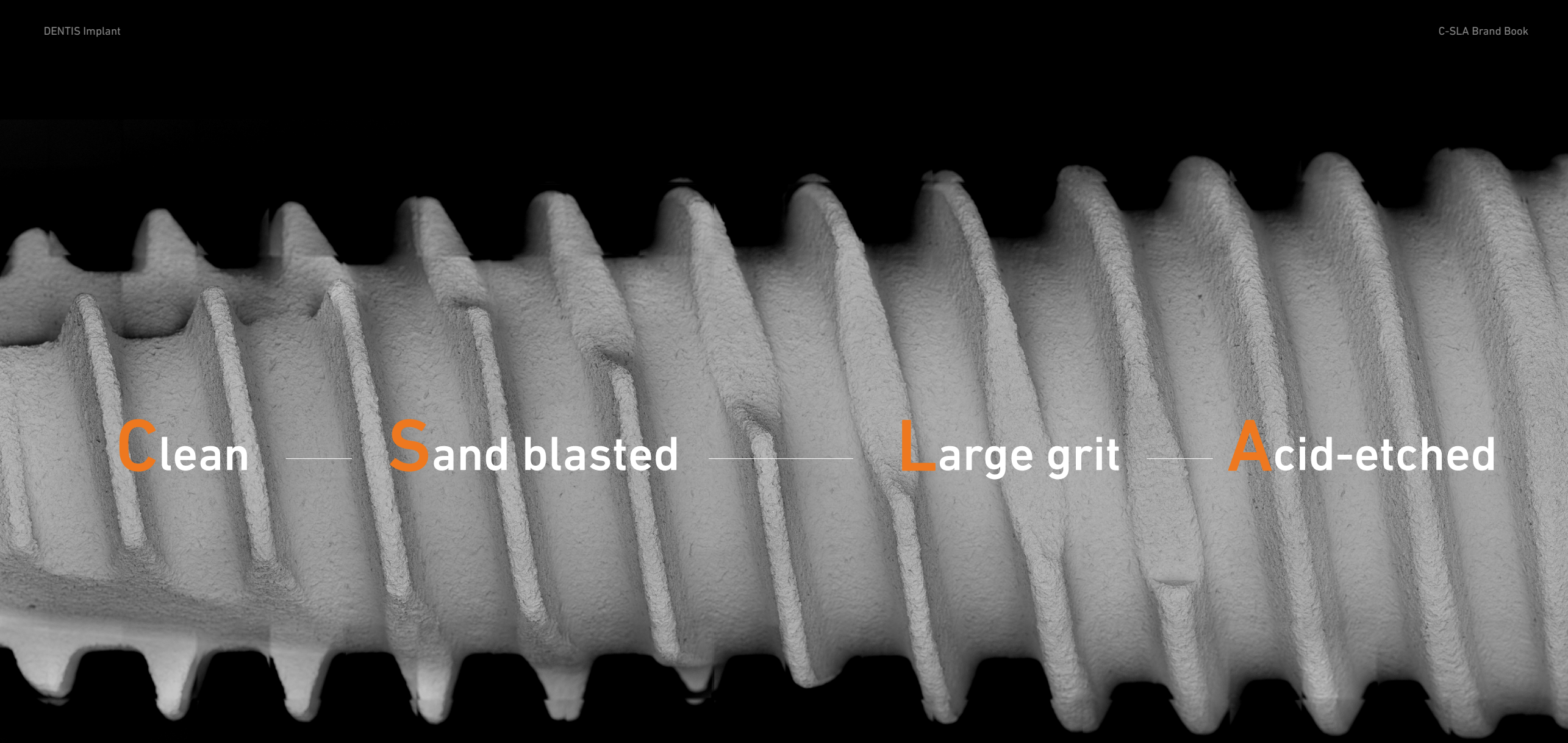
and the upcoming Cube-ASRS logistics automation process,

we invest boldly in modernizing our facilities.

These investments allow us to produce even more consistent, high-quality implants.

Unrivaled brand value maintained since 2006

Clean Implant
Since 2006



Name of examiner : Dipl. Ing. Peter möller msc., Dr. Dirk duddeck

Sample type/material : s-Clean SQ-SL / Ti

Sample identifier : LOT 23E1744A

Test method : Scanning electron microscopic (SEM), energy dispersive x-ray Spectroscopic (EDS) tests by means of imaging enlargements according to DIN ISO 22309:2015-11

Testing instrument : Phenom pro X, desktop-sem

Operating conditions : Laminar-flow-cabin, clean room ISO class 5 (DIN EN ISO 14644-1), normal room temperature

TEST RESULTS (report number: 23-00036-001_DTSsq2807#1)

The material contrast imaging shows only single particles (20-30µm). Elemental analysis of these particles detected signals of aluminum and oxygen, verified by differential EDS measurement as shown in Spot 3 (pp. 13-16). No organic contaminant could be detected within the limitation of the given magnification.

+

TECH

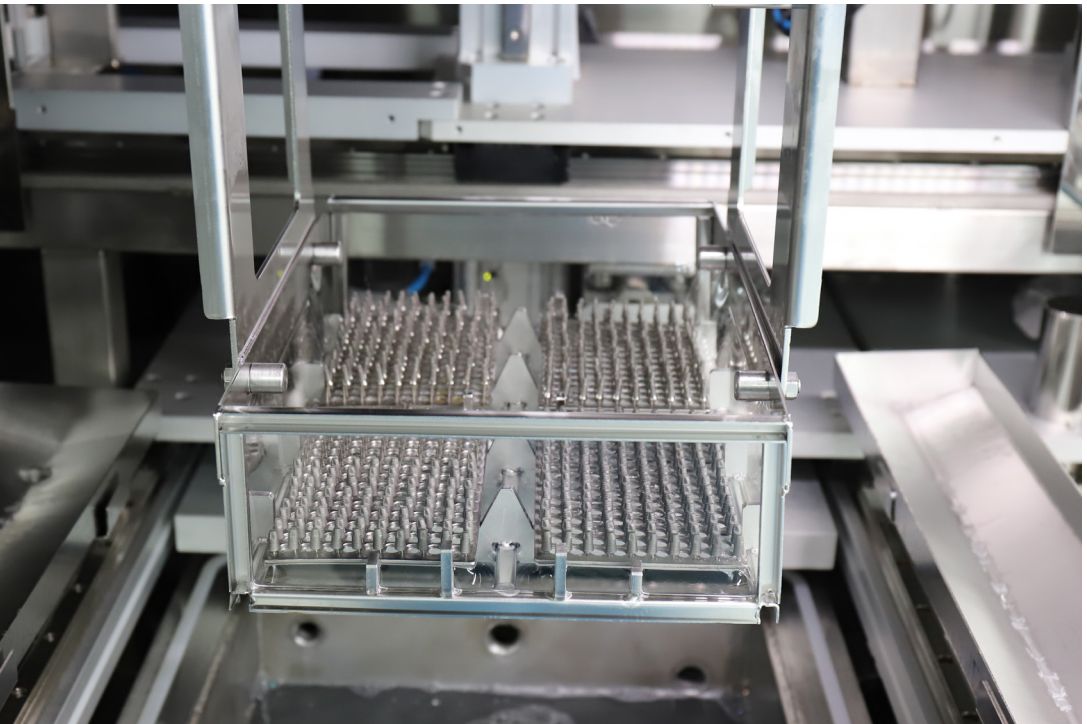
Clean-Tech™'s technological innovation

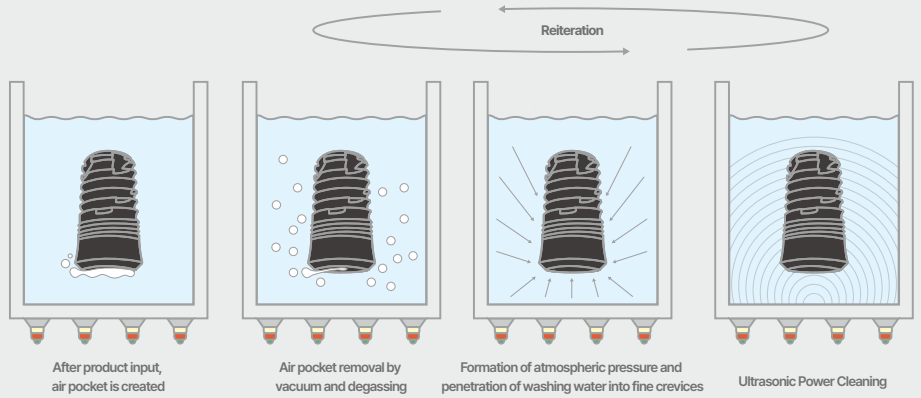
grows into **C-SLA™**.

01
Vacuum Ultrasonic Wave System

To clean the inside of the fixture more thoroughly, we apply a vacuum cleaning method. When cleaning a fixture, there is a problem where an 'Air Pocket' is formed on the inside of the fixture and cannot be cleaned. To solve this problem, DENTIS applies the 'vacuum cleaning method (maximum 5 Torr or less)' to the entire cleaning and rinsing process. Additionally, we applied the 'DI Water' System to make all processes cleaner. It consists of a method of washing the product in flowing DI Water. We minimize the environment in which bacteria or germs can multiply. SUS316L, which has good corrosion and chemical resistance.

Other materials are also made of SUS304, which thoroughly prevents corrosion and environmental pollution caused by nanocrystals.

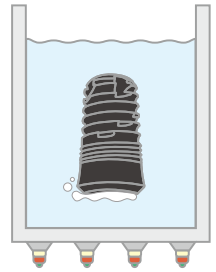




C-SLA™ Vacuum Ultrasonic Method

Creates an air pressure difference to remove the air pocket on the inner diameter of the implant and maximizes the ultrasonic cavitation effect by allowing cleaning water to penetrate and adhere closely.

VS



General ultrasound method

Decreased cleaning power due to air pockets generated on the inner diameter and dissolved gases dissolved in the cleaning liquid.

02

Spherical Wave System

*USDA : United States Department of Agriculture

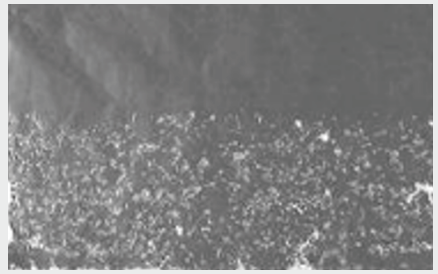
The types of ultrasonic waves can be divided into two kinds: plane waves and spherical waves.

Compared to plane waves, spherical waves have relatively uniform cleaning power.

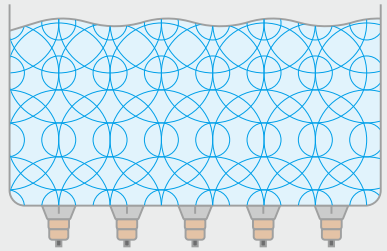
Spherical waveform ultrasound is an ultrasound that complements the diagnostic shortcomings of plane waveform ultrasound and is an expensive ultrasound used in the semiconductor precision cleaning process.

The sweep function of the plane waves is used to compensate for the shortcomings, however, it cannot match the excellent cleaning quality of the spherical waveform. In addition, DENTIS uses a hypoallergenic liquid detergent approved by the *USDA as a cleaning solution. We thoroughly prevent even small amounts of risk by using certified detergents to clean surfaces in Clean Rooms and sterile manufacturing plants that dissolve well in water.

aluminum foil



ultrasonic wave

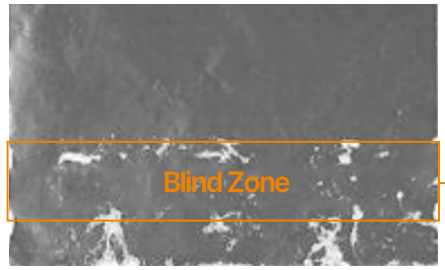


C-SLA™ Vacuum Ultrasonic Spherical Wave System

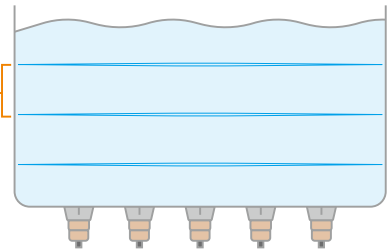
Minimize the non-ultrasonic generation area and enable uniform and stable cleaning with uniform waves.

VS

aluminum foil



ultrasonic wave



Plane Wave, a general ultrasonic method

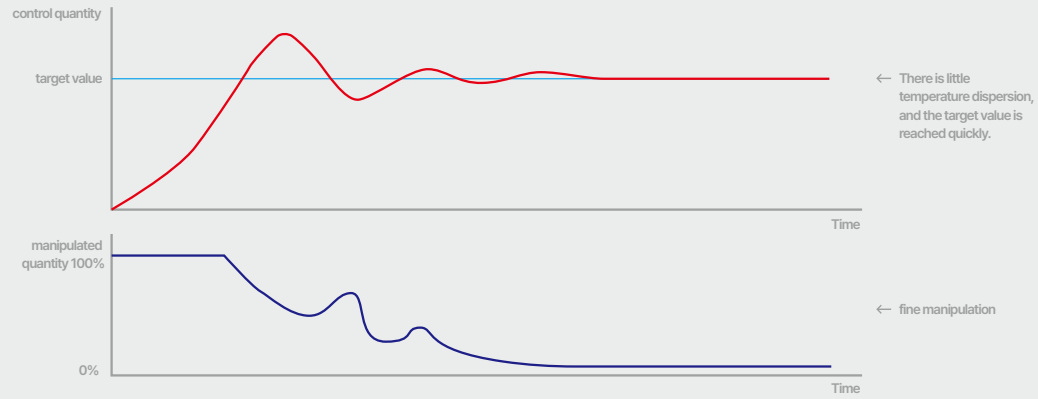
An area where ultrasonic waves do not occur (Blind Zone) is created, and the cleaning is uneven due to rough waves, depending on the shape and location of the product.

03
PID System

* PID : Proportional Integral Derivate

'Temperature condition management' is one of the critical factors in cleaning and surface (acid) treatment. DENTIS adopts the most accurate and stable control method by applying the 'PID System', a real-time calculus temperature control system. General companies use electronic switches or SSR (Solid State Relay) to manage temperature through On/Off control. Still, DENTIS uses SCR (Semiconductor Rectifier Control), a semiconductor rectifier control method, to establish more perfect process conditions and ensure quality.

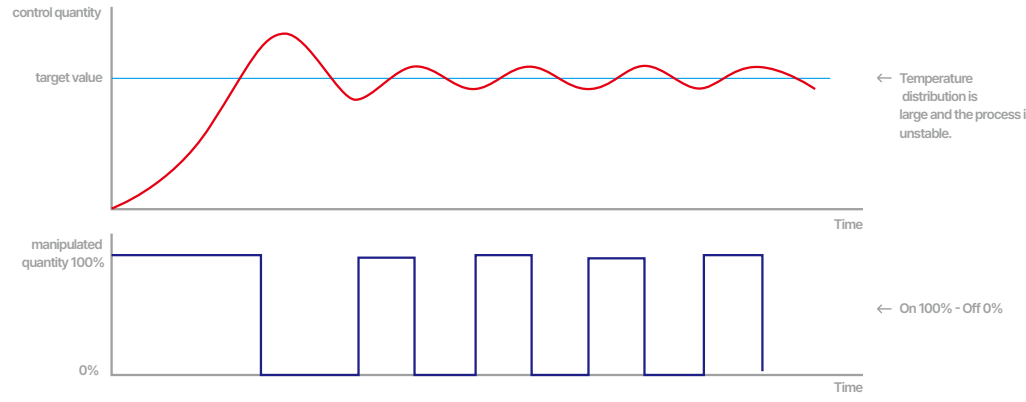
PID control using Silicon Controlled Rectifier is applied.



C-SLA™ PID Control System

Stable process management is possible by reducing temperature dispersion and enabling efficient and detailed operation through automatic control according to temperature differences through PD control.

VS



General On-Off method

Unstable process due to temperature variation

Certification

CLEAN IMPLANT
Trust Quality

The CleanImplant Foundation

Located in the German capital, CleanImplant conducts objective periodical analysis of the production quality of dental implants, by using accredited laboratories according to DIN EN ISO/IEC 17025, based on a defined protocol. Research to determine the consequences and clinical relevance of avoidable contamination and quality deficiencies in dental implants, are promoted and commissioned in collaboration with renowned universities. The Project was initiated in 2016 by Dr. Dirk Duddeck, dentist and biologist, who is working in this field of research for more than 15 years.

According to its statute, the CleanImplant Foundation is a 100% independent organization, that pursues no commercial goals. It is officially registered as CleanImplant Foundation CIF GmbH and works as a non-profit organization. All fundings and revenues are basically to be reinvested and used to improve the performance of the organization. The initiative is committed to scientific and financial transparency.

That means, all processes of analysis are independent and unbiased, reports for the Trusted Quality Mark for residue-free implant systems are peer-reviewed and even the annual financial report is open to public (find out more here).

The awareness campaign is supported by the CleanImplant Foundation (Stiftung), an independent and - according to German law - "charitable" organization under fiduciary administration, located in Werder, Germany. Note: Whenever our Internet pages refer to this organization, we use the German addition "Stiftung" as a reference in the text.

The internationally recognized quality award, the "Trusted Quality" Seal by the CleanImplant Foundation, was created to underline the highest quality of dental implant systems and to give an orientation for all practitioners in the field. Production-site contaminated implants must not longer be accepted!

CLEAN IMPLANT FOUNDATION

TRUSTED QUALITY
2023-2025

This certificate is awarded to

Dentis Co., Ltd.

for the dental implant

s-Clean SQ-SL

The aforesaid implant complies with the CleanImplant Quality Mark Criteria according to the guideline and consensus recommendation of the Scientific Advisory Board released September 2017.

Berlin, January 2nd, 2024

Prof. Dr. Hugo de Bruyn
CleanImplant Scientific Advisory Board

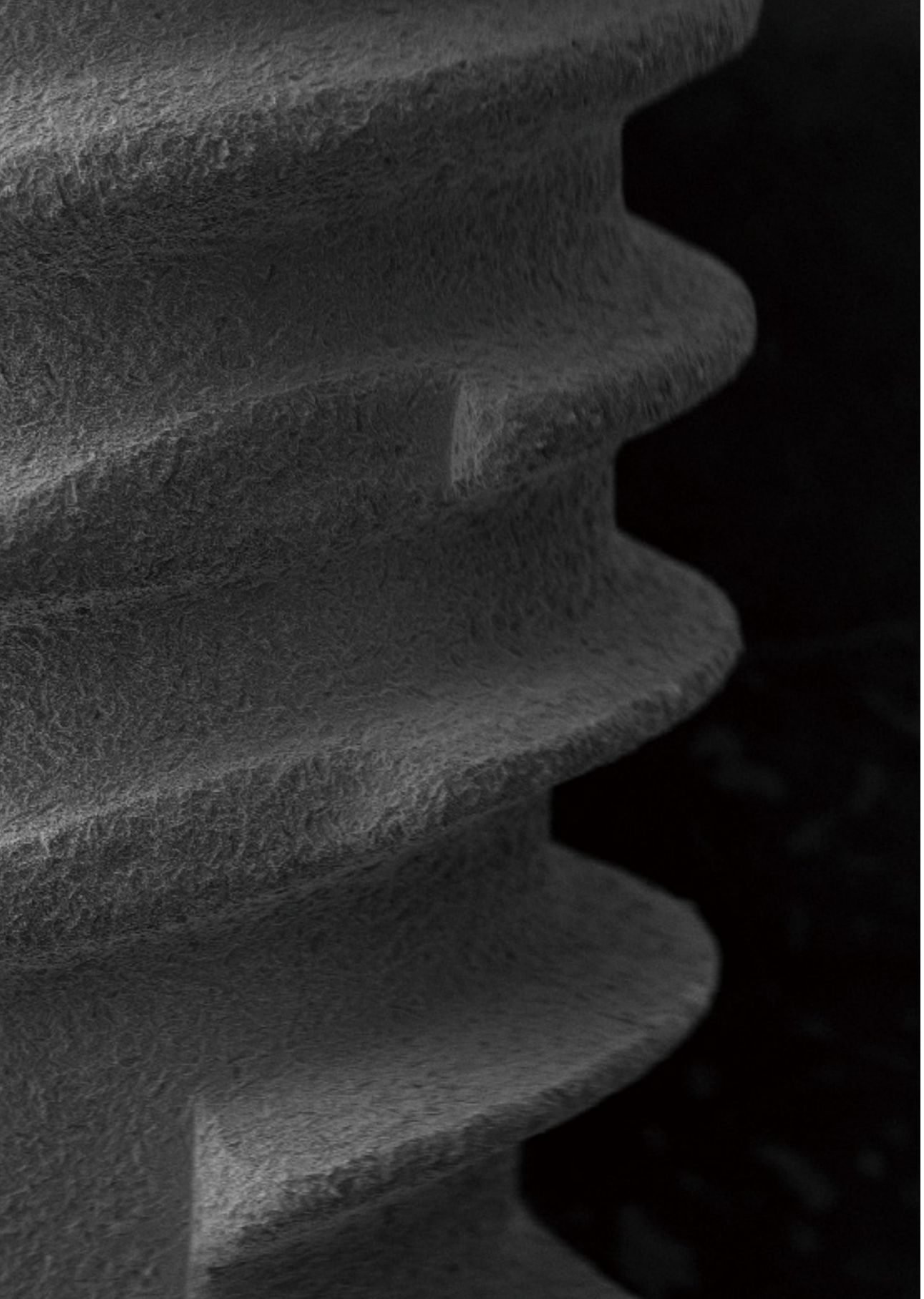
Dr. Luigi Canullo, PhD
CleanImplant Scientific Advisory Board

Dr. Dirk U. Duddeck
Managing Director CleanImplant Foundation

A non-profit organization comprised of world-renowned dentists as advisors. <CLEAN IMPLANT Foundation> issues Trust Quality certifications to products that meet the reliability standards through systematic measurement evaluations for implant products.

Since 2006, DENTIS has been producing Clean Implants, recognized for technological superiority through Clean-Tech™.

As a result, DENTIS has been awarded the **CLEAN IMPLANT Trust Quality Certification 2023-2025** by **'CLEAN IMPLANT Foundation(CIF)'** from Germany.



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PERFORMANCE

Looking forward to infinite possibilities in the future.

A new generation of surfaces, C-SLA™

0%

Residue

clean and safe

Ultrapure implant surface

We meticulously remove **any organic residues and trace elements of titanium**

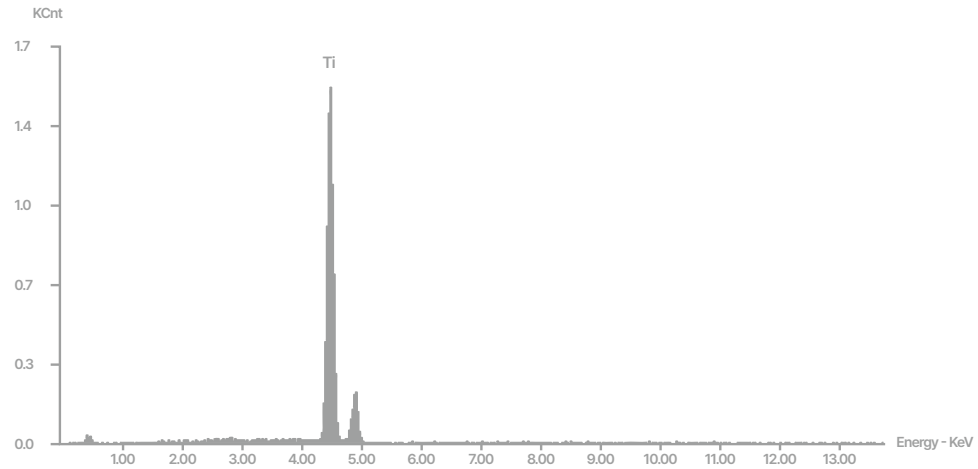
that may exist on the implant surface due to all processes and exposure to air,

ensuring a thorough cleaning process

C-SLA™ Implant is

From the raw material titanium to the entire manufacturing process.

Perfect Cleaning Validation is applied.



Starting with the meticulous selection
of quality-validated raw materials such
as titanium, our manufacturing process
implements comprehensive Cleaning Validation
across all stages.
We install cleaning equipment and rigorously
supervise the post-treatment process to
prevent foreign particles or contamination,
particularly focusing on enhancing corrosion
resistance."

0%

Harmless to the human body

Through residue biocompatibility analysis and cytotoxicity verification,

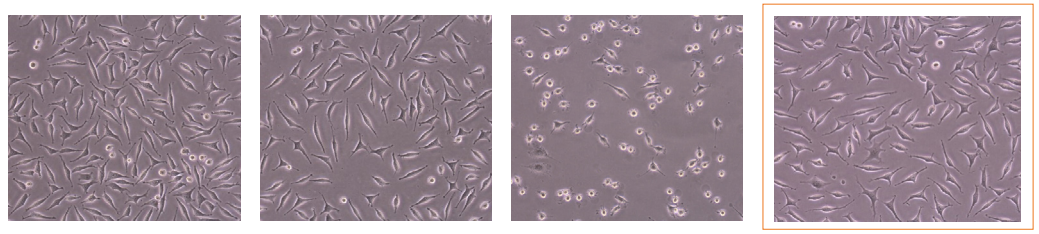
an Ultra Safe Implant Surface

Since its pioneering development in 1997 and subsequent extensive clinical validations recognizing its exceptional osseointegration capabilities, the SLA surface has gained widespread popularity. However, due to **potential risks associated with residue** from the aluminum oxide blasting process and acid etching process, thorough cleaning is imperative

C-SLA™ Implant with DENTIS' Clean-Tech™ applied

As an ultra-pure SLA surface without residue, it eliminates the risk caused by residue, ensuring clinical safety.

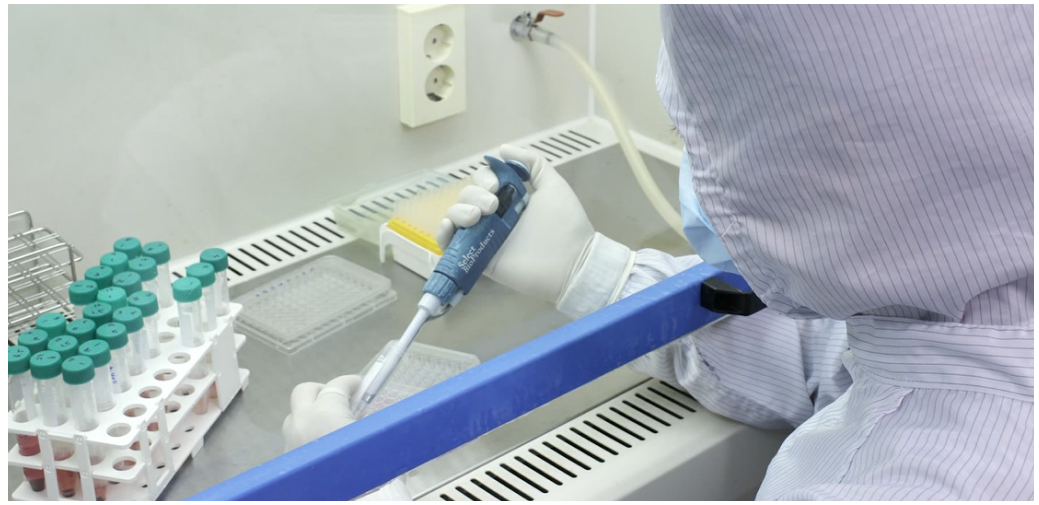
Cytotoxicity test



a. Media control group | b. Negative control group | c. Positive control group | **Test group (DENTIS)**

element	F-	Cl-	NO2-	SO42-	NO3-	PO43-	Si	Ca	Al	Na	P	Cu	Zn	Fe
DENTIS	0	0.01	0	0.01	0.01	0	0.01	0.01	0	0	0	0	0	0

< 2023Surface residue composition analysis results >



0%

No Lot Defects

Thorough tracking management and perfect quality control. Reliable, **high-quality implant.**

To improve tracking management convenience and productivity, **we thoroughly manage production history from the receipt of raw materials.**

In addition, through individual LOT management of the final products, **C-SLA™ is recording an unprecedented performance of 0% LOT defect rate.**

Case Study

Implant Stability Measurements in the **Long-Term Follow-up** of DENTIS Implants: A Retrospective Study With Periotest

Mi-Ae Jeong, RDH, PhD,* Mi-Kyung Jung, DDS, MSD,† Su-Gwan Kim, DDS, PhD,‡ and Ji-Su Oh, DDS, PhD§

Purpose:
The purpose of this study was to evaluate retrospectively the stability of DENTIS implant with the Periotest.

Methods:
In total, 36 patients and 88 implants were investigated. Periotest was used to measure implant stability, and a periapical view was taken immediately after surgery and again immediately after, 3 months after, 6 months and 5 years after prosthesis placement. Bone loss on the periapical view, bone quality according to tactile sensation, and area of implant installation were assessed.

Results:
The mean Periotest value (PTV) immediately after surgery was −1.02, and the mean bone loss rate (bone loss/fixture length 3 100) at 6 months after prosthesis placement was 8.42%.

PTV was higher with more bone loss (types III, IV vs types I, II bone). The lowest mean PTV was in the lower molar area (−1.48), followed by the lower anterior (−1.41), upper molar (0.11), and upper anterior area (5).

One implant failed and survival rates were 98.9%.

Conclusion
: Implant stability was lower in cases with more bone loss and poor bone quality and in the maxilla versus the mandible.
(Implant Dent 2015;24:263–266)

Table 4. PTVs According to Bone Quality

Periods After Implant Placement	Type I	Type II	Type III	Type IV
Immediately after surgery	-3.52	-2.03	-1.88	2.34
Immediately after prosthesis	-4.43	-2.54	-2.42	1.78
3 mo after prosthesis	-4.52	-2.66	-2.49	1.69
6 mo after prosthesis	-4.59	-2.8	-2.64	1.55

Type I: mainly very thick cortical bone, Type II: dense cortical and cancellous bone, Type III: thinner cortical bone and less dense cancellous bone, Type IV: very thin cortical bone and sparse cancellous bone.

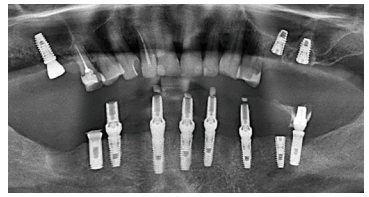
Table 5. PTVs by Implant Placement Location

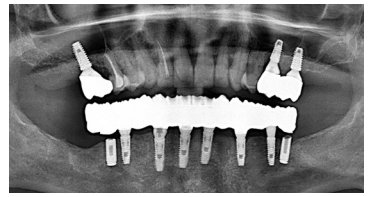
Periods After Implant Placement	Anterior Maxilla	Posterior Maxilla	Anterior Mandible	Posterior Mandible
Immediately after surgery	5	0	-0.44	-1.68
Immediately after prosthesis	5	-1.57	-1.14	-2.25
3 mo after prosthesis	3	-1.68	-1.25	-2.31
6 mo after prosthesis	3	-1.72	-1.32	-2.41
5 y after prosthesis	-	0.2	-5.9	-0.24

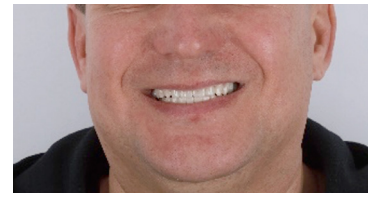
Case Report

Rehabilitation of a patient with partial secondary adentia of the upper and lower jaws using dental implants

Vyacheslav Kvashov, DDS


Treatment (Lower jaw/Upper jaw)


Panoramic X-ray after treatment


Results

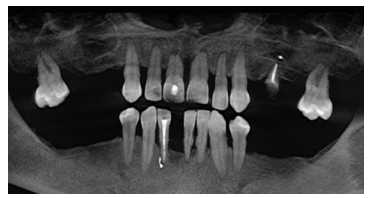
Introduction
Having been working with One Q-SL implants for several years, we are convinced of its reliability and versatility. With the help of these implants, any clinical case can be closed. They have proven themselves well both with Immediate placement , and with immediate loading, and in cases of Immediate placement when performing a sinus lift. One Q-SL has all the necessary orthopedic components to achieve the best functional and aesthetic results!

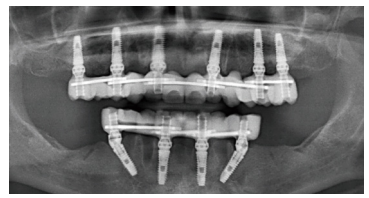
Age : 52yr / Sex : Male
Complaints of aching pain in the teeth of the upper and lower jaws, violation of aesthetics. There are bridge structures based on implants and teeth installed about 15 years ago. 2 implants are bare by 1-2 mm, one is half of its length.

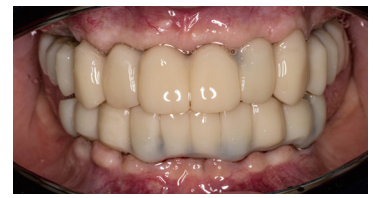
Conclusion
This case fully confirms the versatility of the OneQ-SL line. A number of different implant operations have been performed and in each of them we have used these implants. We are confident that the new smile will serve our patient for many years to come.

Guided surgery as the key to predictability and high aesthetic results

Oleg Tukhvatullin, DDS, PhD


Diagnosis: partial secondary adentia


Panoramic X-ray after treatment


Results

Introduction
Nowadays, by virtue of rapidly advancing technologies in the field of dental implantation, it is possible to solve clinical cases, that were remediless just a few years ago. At the same time, patients become more demanding. The duration and comfort of the treatment, as well as highly aesthetic results are very important for competitiveness. Thereby, need for utilization of digital protocol and navigational surgery is as high as ever

Age : 62yr / Sex : Female
Came to the clinic for the restoration of the teeth of the upper and lower jaws. She wants to restore masticatory function and acquire a beautiful smile.

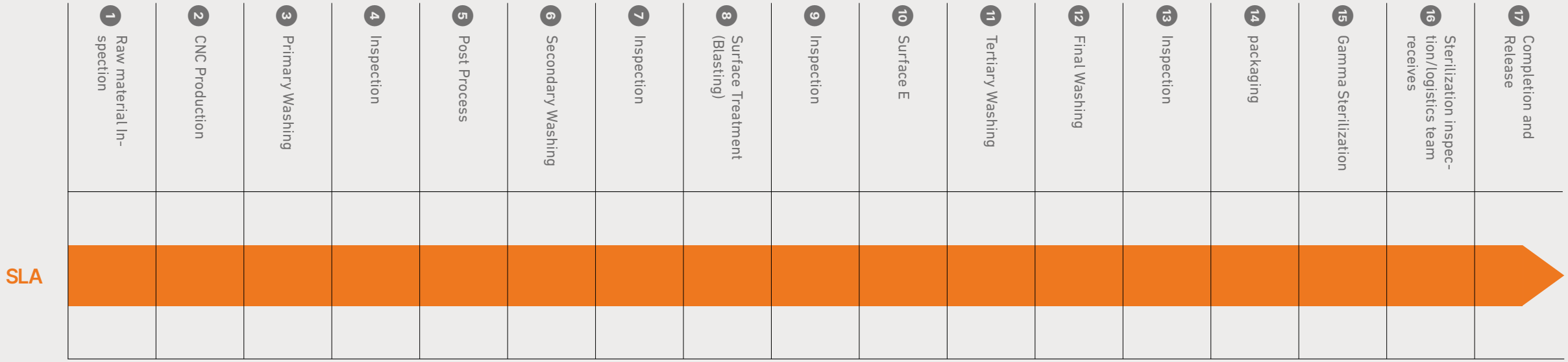
Conclusion
The digital protocol includes two important points: Firstly, preplanning of the denture and surgical intervention steps prior to the treatment. Secondly, precise implant placement using navigation kit and surgical guide, which ensures minimally invasive work. Thus, this particular approach
allows predictability of the end result, as well as fast recovery period.
Furthermore, not only patient is satisfied with aesthetics, comfort and treatment speed, but dentist can be confident with long lasting service of implants and dentures!

C+™

+

FACTORY

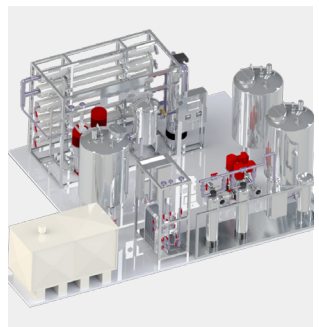
CLEAN FACTORY,
Beyond Cleanness to Pureness



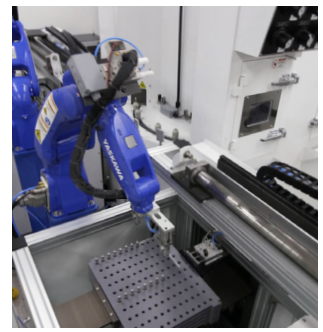
Applied Advanced Technology:
DENTIS Smart Clean Factory

Beyond cleanliness by adding cutting-edge systems
DENTIS' progress toward purity does not stop.

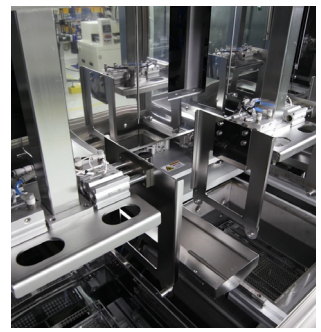
ME Zone(Mini Environment Zone)



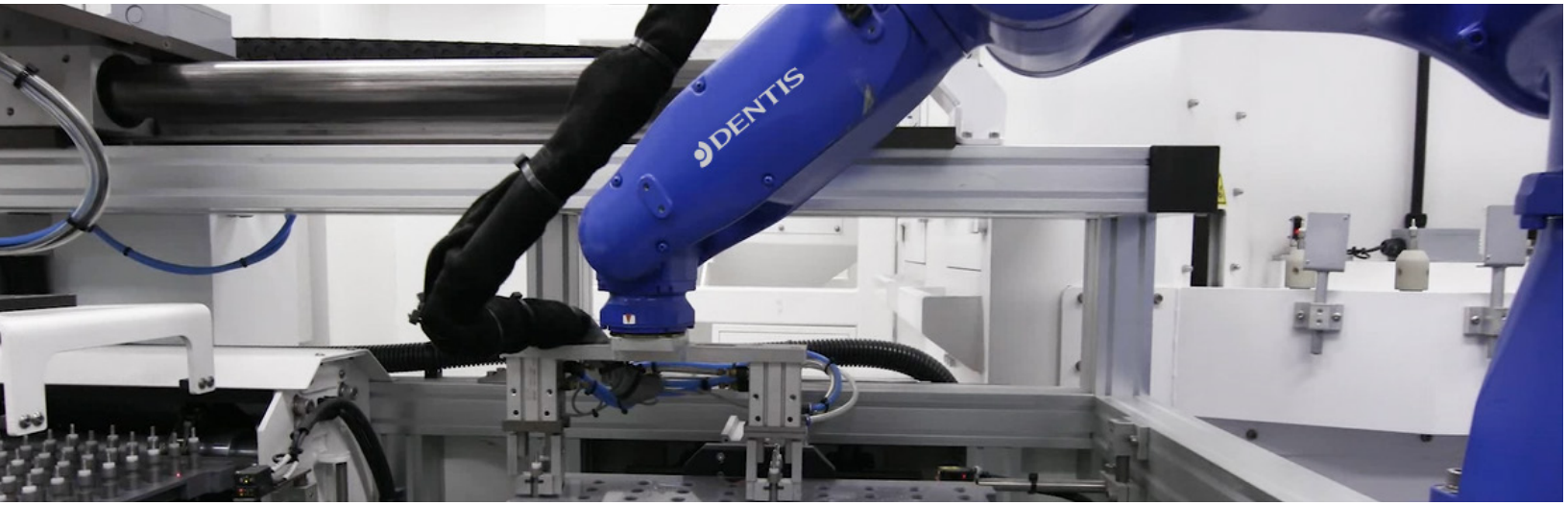
Use ultrapure washing water

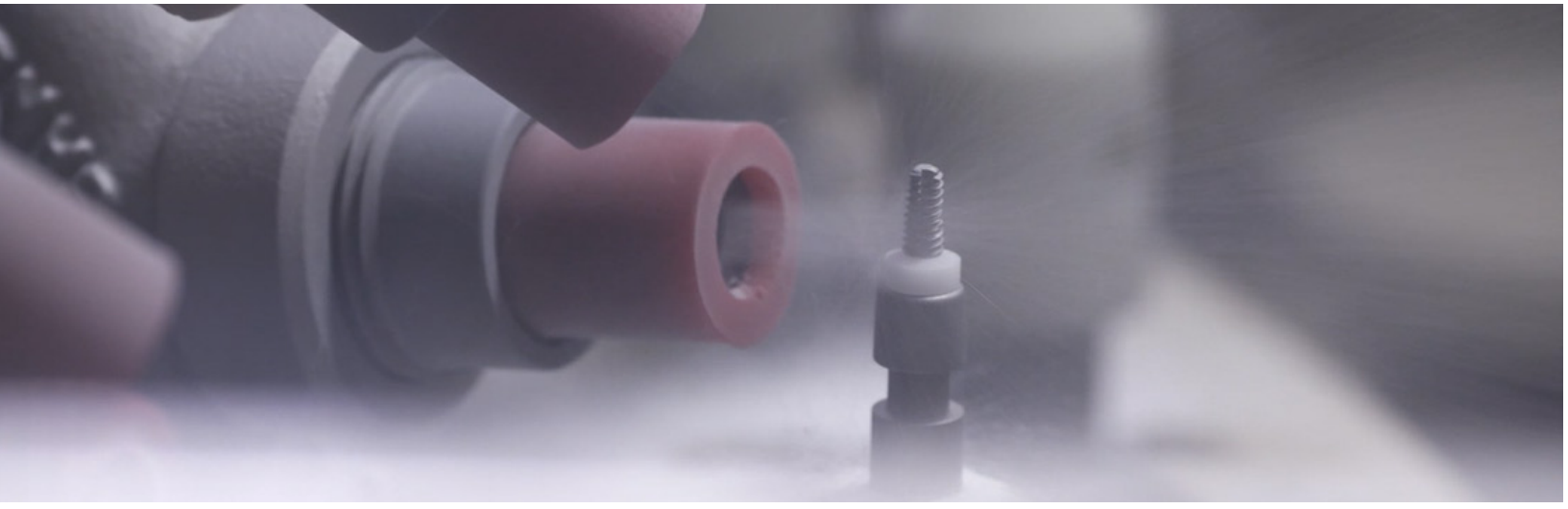


Robot automation equipment



Multi-tank dishwashing





Clean-Tech™ applied! Only DENTIS completes the surface

Surface technology diversified,

quality management heightened.

SLA

26 steps of cleaning process

4·6·6·3·7

The ‘driving force’ that protects DENTIS’ heritage of ‘CLEAN’

DENTIS’ firm belief in ‘
making clean implants’ never changes.

01

Precise and uniform cutting-edge quality control using ultra-precision equipment and robot automation

02

Ultrapure vacuum ultrasonic method, Korea’s most considerable cleaning process

03

After final packaging, 100% gamma sterilization and sterilization inspection. Final validation verification

04

Application of Clean Tech™ to completely block rust and bacterial growth in manufacturing facilities (proprietary design)

CLEAN C-SLA™

Be sure to check

the C-Mark!

Completed with Clean-Tech™ from

DENTIS Smart Clean Factory,

Clean-SLA surface implant!

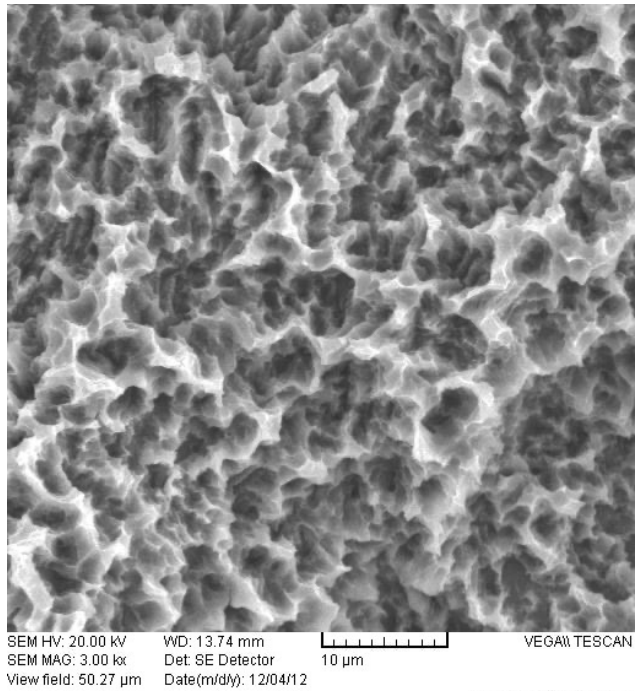
You can experience **unrivaled technology and brand value.**

Check out the best clinical results for yourself.

Application period and design may vary by country.

Innovatively widened contact surface for
broader and safer osseointegration

REAL surface area of C-SLA™.



Check out various clinical data on implants with C-SLA™ surface

Clinical Videos

DENTIS introduction