NiTi brush for Peri-implantitis

HANS Korea

What is now proved was once only imagined

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The Origination of the NiTi Brush for Peri-implantitis

The original idea of this NiTi Brush for Peri-implantits had been supplied by Professor Dr. Baek-Soo Lee - Department of Oral and Maxillofacial Surgery, Kyung-Hee University, Seoul , Korea &
DDS, PhD, FITI - Oral Surgeon Yasushi Nakajima in Osaka, Japan.

I would like to personally thank and acknowledge the smart idea for the treatment of peri-implantitis from Professor Dr. Baek-Soo, Lee and Dr. Yasushi Nakajima.

HANS Korea established in 2010 for the NiTi Brush business and the first commercial version of NiTi Brush released at the annual meeting of American Academy of Periodontology in 2011.

Intended use of the NiTi brush for peri-implantitis

[Intended Use]

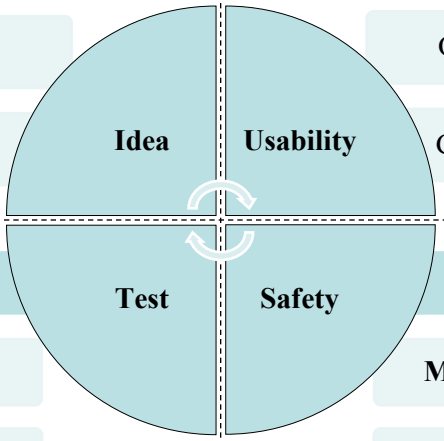
NiTi Brush for peri-implantitis is intended for mechanical debridement and cleaning of titanium dental implant surface contaminated by osseous defect of plague, calculus or any other foreign body materials resulted from peri-implantitis, and NiTi Brush for peri-implantitis is designed for use in dental office by dentists, dental hygienists and trained dental assistants.

NiTi brush for peri-implantitis is “Non-sterile” products. **Sterile must be done before use.**
For more information, please refer to the information for use.

NiTi brush for peri-implantitis is single time use only. **DO NOT RESUE.**
For more information, please refer to page

History of the NiTi brush for peri-implantitis

The developement protocol of NiTi brush for peri-implantitis.



Use mechanical cleaning.		Design	**Material**
Debride the implant surface.		**Own Patent**	Shank & Bristle
Return to the machined surface.		One design?	**Flexibility**
Using a “metal base bristled brush”.		Compatible?	**Hardness**
1st in vitro performance test.		Same Material & different design	
2nd in vitro performance test		**Material of Bristle : NiTi(ASTM F2063)**	
Clinical case report from the clinic.		**Material of Shank : SUS(iso1797-1/metal)**	
Publications resulted from the in vivo test.		Scientific evidence of NiTi as a dental device.	
New designs resulted from the customer feedback.		Patented designs and excellent compatible.	

History of NiTi brush for periimplantitis

Year 2010, We released the first “Concept Products”.

The Concept Product worked better enough than we had been expected.

Few Pioneers started to use the Prototype.

And we have been discussed with

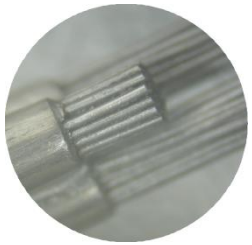
the Pioneers for more

development.

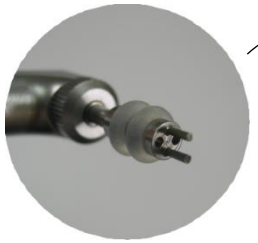
Present : 4 types of brushes

- ✓ Pocket
- ✓ Micro
- ✓ Nano
- ✓ 2D Long

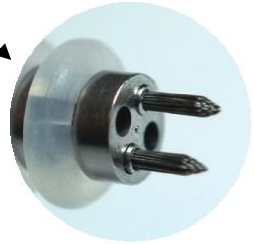
2013
Curled wire brush



2010
Concept Model



2011
Prototype



2011
Conical wire & brush

2012
Remove Elastic

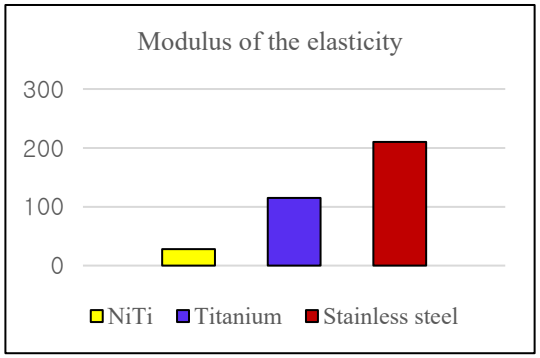
Why the NiTi as the raw material of bristles ?

NiTi has the best mechanical property for debridement of titanium based dental implant surface.

- ✓ **NiTi is 3 times more flexible than titanium.**
- ✓ **NiTi has similar hardness with titanium.**
- ✓ **NiTi can debride the implant surface with less damage.**

Comparison the mechanical property of Titanium, NiTi and Stainless Steel

	Titanium	**NiTi**	Stainless steel
modulus of the elasticity	115[1]	**28~41[2]**	210[3]
Hardness (Vickers)	200~340[4]	303~362[5]	600-610[6]



- ➢ We can say that the NiTi bristle could be more effective than the titanium bristle for the debridement of titanium based dental implant surface.
- ➢ Stainless steel is very hard material and it has less flexibility comparing titanium. So stainless steel would not be suitable material for the debridement brush of dental implant surface.

Understanding of modulus of elasticity:

The modulus of elasticity of diamond is 1,000-the top level of the sheet and the rubber is the one the lowest level of the sheet. Smaller modulus of elasticity means “more flexible”

Reference of data sheet "Comparison the mechanical property of Titanium, NiTi and Stainless Steel." in page 8.

[1] Carlos Oldani and Alejandro Dominguez (2012). Titanium as a Biomaterial for Implants, Recent Advances in Arthroplasty, Dr. Samo Fokter (Ed.), ISBN: 978-953-307-990-5, InTech,
http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.661.8190&rep=rep1&type=pdf

[2] J. Ryhanen, E. Niemi, W. serlo, E. Niemela, P. sandvik, H.Pernu., T. salo "Biocompatibility of nickel-titanium shapememory metaland its corrosion behaviorin human cellculture"J Biomed Materres Jun 15,35(4),451-7 1997.

[3] Same reference with [1]

[4] Vickers hardness of cast commercially pure titanium and Ti-6Al-4V alloy submitted to heat treatments
Sicknan Soares da Rocha[I]; Gelson Luis Adabo[I]; Guilherme Elias Pessanha Henriques[II]; Mauro Antônio de Arruda Nóbilo[II]
[I]Department of Dental Materials and Prosthodontics, Faculty of Dentistry of Araraquara, São Paulo State University, Araraquara, SP, Brazil
[II]Department of Periodontology and Prosthodontics, Faculty of Dentistry of Piracicaba, State University of Campinas, Piracicaba, SP, Brazil
http://www.scielo.br/scielo.php?pid=S0103-64402006000200008&script=sci_arttext&tlng=pt#tab2

[5] Nickel–titanium: options and challenges by Michael A. Baumann, DDS, PhD, Univ.-Prof. Dr. med. dent. Department of Operative Dentistry and Periodontology, Dental School, University of Cologne, Kerpener Strae 32, D-50931 Ko¨ln, Germany
http://endoexperience.com/documents/nitioptionsandchallenges.pdf

[6] Same reference with [5]

GMDN code : 57955(Dental implant debridement brush)

Product name : NiTi brush for peri-implantitis

Product image	Model name	Difference in Use
	Nano(Non-flap case)	Narrow brush for very targeted area. Ex. Debride the micro thread. Very Precise & accurate operation
	Pocket(Flap open /Anterior)	Most widely used brush – the regular brush.
	Micro(Flap open / Molar)	Same design with Pocket But, 5mm shorter for Molar area
	2D Long	More effective in cleaning wide area

The description of the NiTi Brush

Two types of bristles have similar function but the small difference could be needed in operation

ICT POCKET and MICRO

ICT NANO and 2D LONG

Curled & Spread out – Spring effected wires

Conical shape of brush tip for precise operation

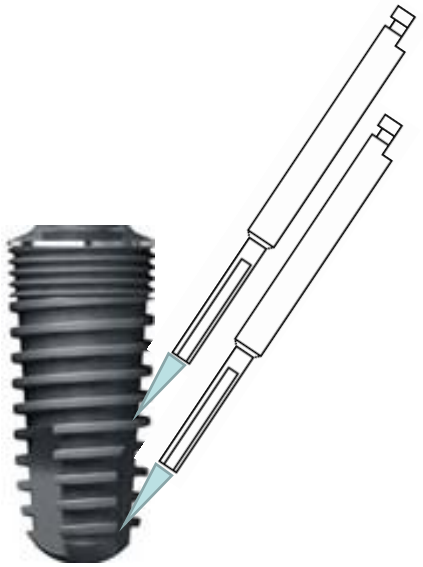
The direction and method of brushing

In case of :

Cleaning the one side of implant, or some area of implant,

Move the brush top-down and horizontal directions

- Touch & back, touch & back technique.



- Slightly touch the brush on the surface of implant.
- Repeat “Touch and back”
- Access to the bottom of thread and back.
- Slide down the brush through the “top-down” direction.
- Plenty of irrigation is essential.
- RPM 600 – 1200 acceptable.

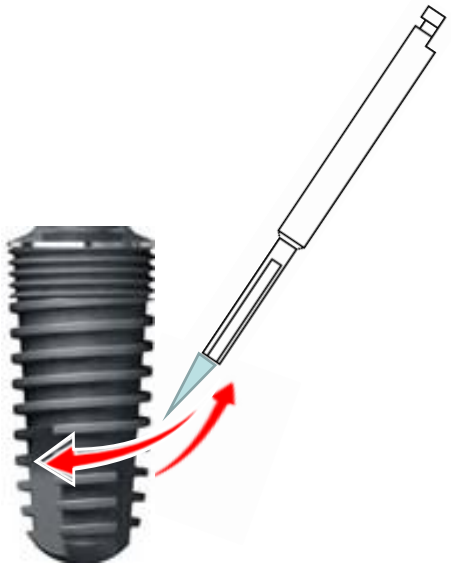
The direction and method of brushing

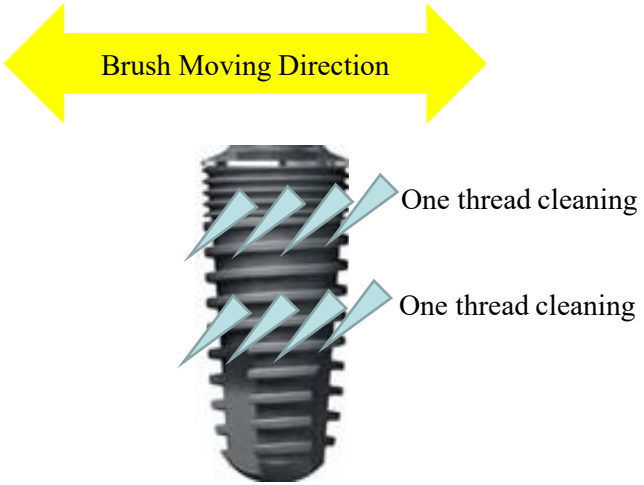
In case of :

Cleaning the thread one by one,

Clean the one thread and clean the next thread.

- Brush must be accessed into the bottom of the thread.
- Move the brush through the side direction-right and left, left and right.
- Repeat the side-direction movement through the one thread.
- Around RPM 600~1,200 could be suitable..
- Enough irrigation could be helpful for slowing down the speed of “wear away” of the bristles.





Debride even the bottom of the implant thread

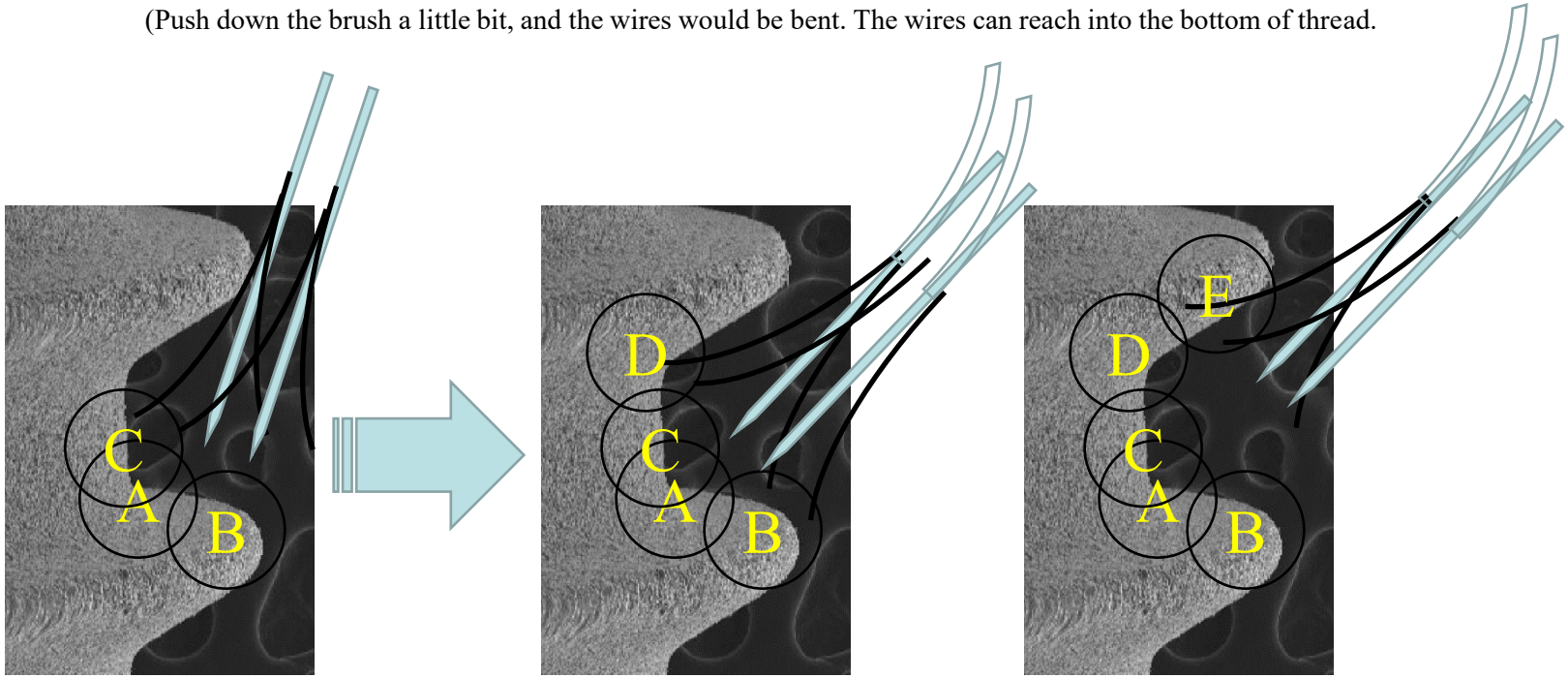
For understand of working mechanism - accessible and cleanable area **Model name : ICT NANO & ICT 2D Long**

Suppose 1 : Only two pieces(Diameter 0.09mm, NiTi) of wires in handpiece.

Suppose 2 : “Centrifugal force” by rotation of handpiece.

Suppose 3 : “Physical force” by doctor’s hand.

(Push down the brush a little bit, and the wires would be bent. The wires can reach into the bottom of thread.



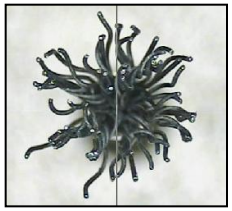
“A”, “B”, “C”, “D” & ”E” are Accessible & Cleanable

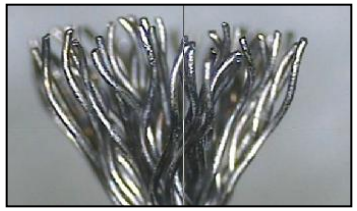
Debride even the bottom of the implant thread

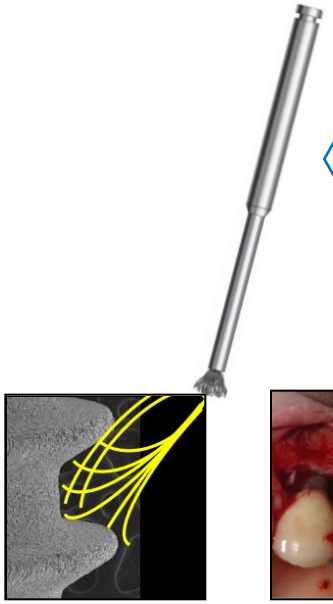
ICT-Pocket(and Micro) for (more easy) horizontal access from vertical direction !!!

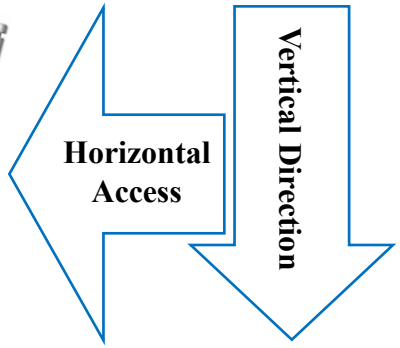
More effective design for debridement form the vertical direction

ICT-POCKET(&MICRO) composed by curled wires, and these **curled wires** received a special "heat treatment". This special curled wires-spring shaped(spring effect), have "more-flexibility" and "less-strength". Further more, the enough "inter-wires-space" boost up the efficiency for the brush to debride the implant surface: More effective in debridement of implant surface-even the deep bottom of thread.









Before

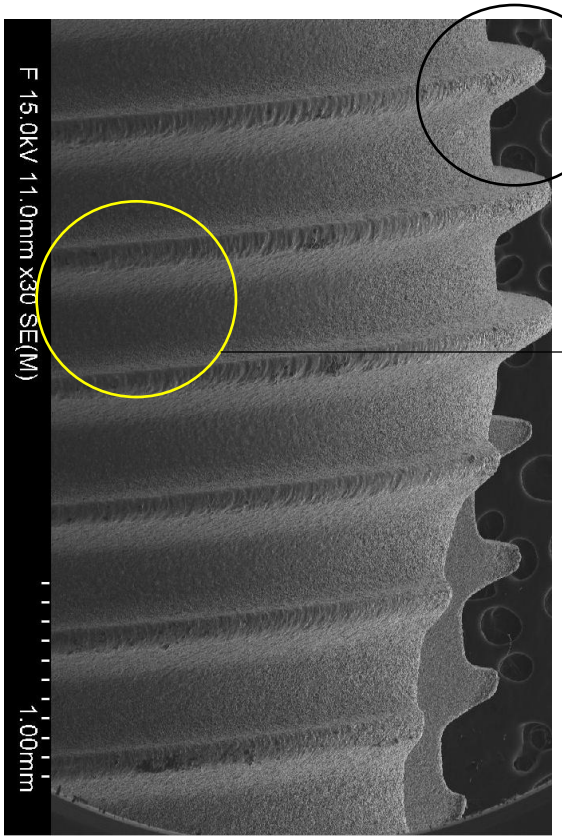
After

The performance of the NiTi brush for peri-implantitis

Main purpose of NiTi Brush – Return to the smooth surface

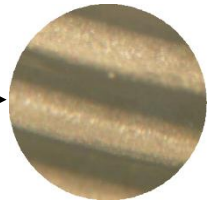
Make the rough surface into to the smooth(machined) surface

Debridement



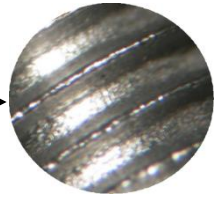
Not cleaned Surface

Rough Surface



Cleaned Surface

Machine Surface



NiTi brush changes the implant surface into the “machined(smooth) surface”

Remove the space for biological material to stay.

The performance of the NiTi brush for peri-implantitis

3 minutes of limited debridement using different brushes in different implants

24 implants that stored in normal condition for 12~60 months after removing from patients

Before

After

Before

After

Regardless the design of brushes, both operation “without removing the crown” or “removing the crown” is possible.

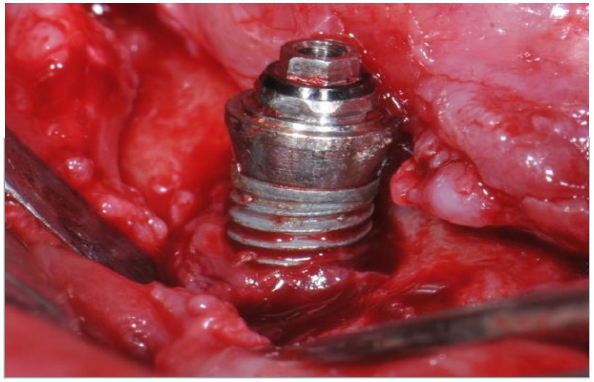
Operation after removing crown

Without removing crown

Clinical operation with crown & without crown

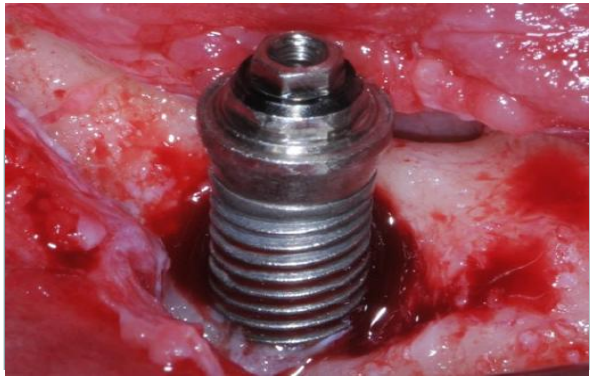
The SEM images of implant surface(before & after brushing).

Before

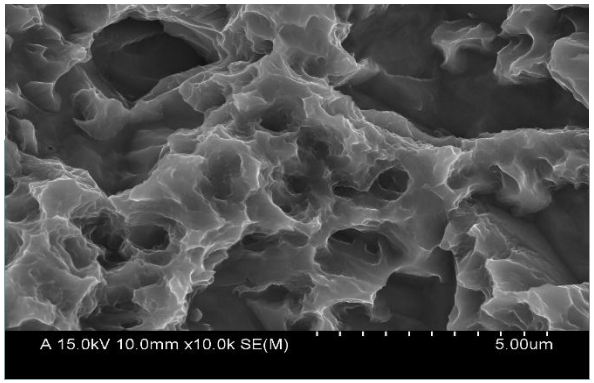


Not cleaned surface

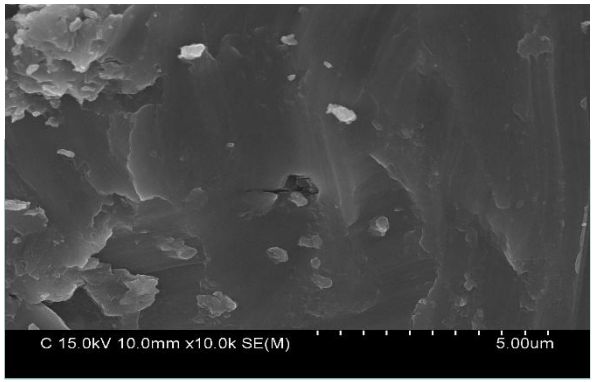
After



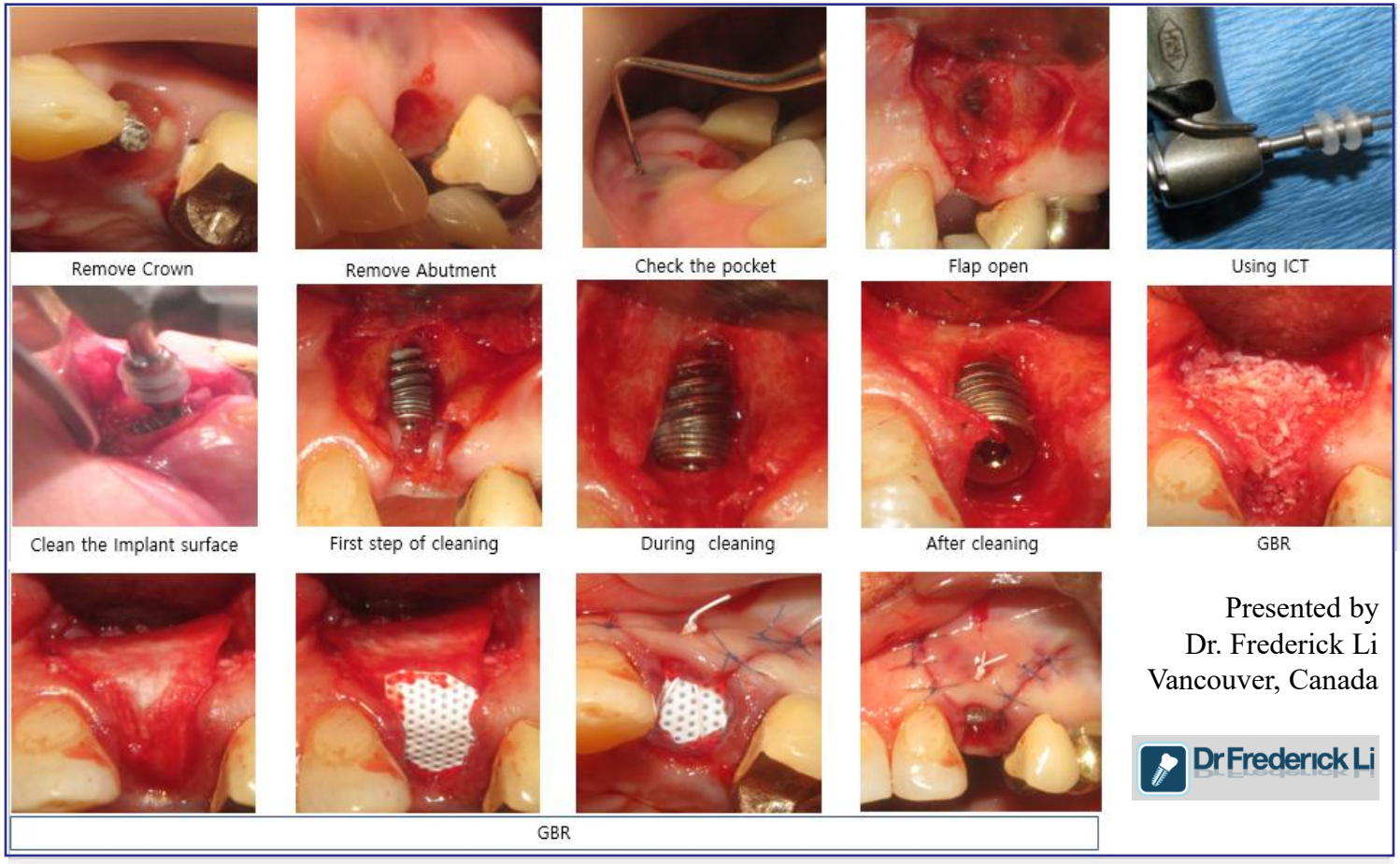
Cleaned surface by ICT



Not cleaned surface(x10k bigger image by SEM)



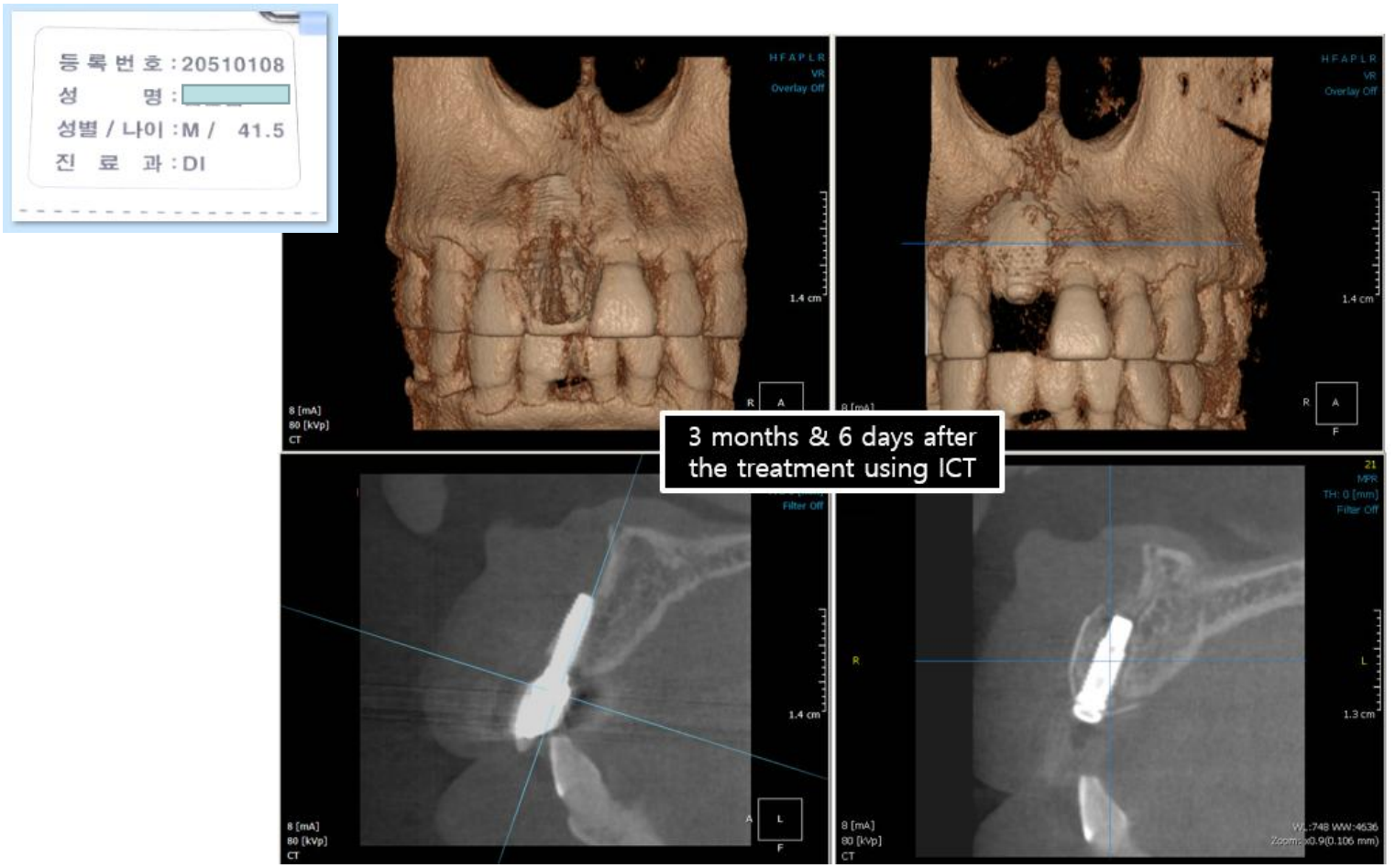
Cleaned surface(X10k bigger image by SEM)



After brushing, citric acid or(and) tetracycline could be helpful for detoxification and better result.

Example) Using Citric acid Ph=1, do the burnish for 3 minutes then wash it away.

And Tetracycline 250mg placed in 2.5cc water then do the burnish for 3 minutes then wash it away.


등 록 번 호 : 20510108
성 명 :
성별 / 나이 : M / 41.5
진 료 과 : DI
3 months & 6 days after
the treatment using ICT

[Intended Use]
NiTi Brush for peri-implantitis is intended for mechanical debridement and cleaning of titanium dental implant surface contaminated by osseous defect of plague, calculus or any other foreign body materials resulted from peri-implantitis, and NiTi Brush for peri-implantitis is designed for use in dental office by dentists, dental hygienists and trained dental assistants.

[Indication] : Peri-implantitis disease

[Side Effects] : Discomfort, Swelling

[Contraindications]
It is contraindicated in young patient with poor attention and it can't be used in non-implant surgery patients.

[Patient Population]
Ages : adult
Weight : Multiple
Race : Multiple
Patient condition : The NiTi Brush is used for patients who have dental implants.

[Intended Operator]
Education : Expert trained who can use this medical device.
Knowledge : Medical Knowledge
a) Read and understand 'westernized Arabic' numerals when written in Calibri font
b) Can distinguish: left arm, right arm
c) Understand hygiene
Language : English or German (Languages offered in the instruction for use)
Experience : Use by dentists, dental hygienists and trained dental assistants

[Checklist before Use]
Recommended temperature for operation room is 15℃~30℃.
The reactions of patient against or incompatibility with titanium or nickel.
Visual inspection for breakage of package.
Visually inspect the damage, breakage, deformation, pollution from any foreign material in NiTi Brush.
Sterilization method.
Preparing recommended handpiece for NiTi Brush.
Preparing sterile saline solution(NaCl) for irrigation and cooling.
Preparing 3% hydrogen peroxide solution for the multiple use in one patient using one NiTi Brush
Understanding of instruction for use.

[How to Use]
1. Open the outer box and pick the inner plastic box up.
2. Open the inner plastic box and pick the NiTi Brush up
3. Inspect the NiTi Brush for defects
4. Pack the NiTi brush into the sterilization pouch
   Sterilize the NiTi Brush using autoclave.
5. Attach the NiTi Brush in sterilized handpiece.
6. Position the NiTi Brush to clean the targeted dental implant then clean the dental implant.
7. Rinse extensively with sterile saline solution throughout the whole brushing time.
8. In case of multiple use in one patient using one NiTi Brush, it is recommended to immerse the NiTi Brush in a 3% hydrogen peroxide solution and rinse with sterile saline before clean or debride another implant.

[How to connect between NiTi brush and Dental Handpiece]
Recommended handpiece for NiTi Brush is the CE marked rotating low speed handpiece.
Any handpiece that has the deceleration rate of "20:1" is recommended.
Recommended RPM for operation is 600RPM ~ 1,200RPM.

[Caution]
Only use by dentist or dental hygienist and trained dental assistants

[Warning]
NiTi Brush must not be used in patients reporting reactions against or incompatibility with titanium or nickel.
Do not use the brush in the broken inner plastic box.
In case of damage, breakage, deformation, pollution from any foreign material in NiTi Brush, do not use it.
NiTi Brush is non-sterile product.
NiTi Brush must be sterilized according to the sterilization method & condition of instruction for use.
After sterilization, use the NiTi Brush without re-packing or re-storage.
Because of the risk for cross infection from patient to patient, NiTi Brush should be discarded after use.
NiTi Brush is for single-use only. Do not re-use the NiTi Brush.
Do not use if expiration date has been exceeded.
NiTi Brush must be used in accordance with the instructions for use provided by the manufacturer.

[Sterilization Method & Condition]
Preparing the sterilization of NiTi Brush and sterile the NiTi Brush in accordance with bellow condition.
Autoclaving Procedure
Keep the NiTi Brush in the sterilization pouch (or Sterilization Wrap)
to keep it clean until you use it.

Sterilization Condition]

Sterilization Method	Autoclave
Configuration	Wrap
Temperature	134 ℃
Pressure	2.5 bar
Exposure Time	15 minutes
Dry Time	20 minutes

[How to Disposal]
Manage the NiTi Brush according to the rules and guidance of the disposal
for disposable medical device.

[How to Storage]
Recommended temperature for storage is 15℃~30℃.
Recommended humidity is 1% ~ 75%
Keep away from the sunlight.
Do not load or store any other materials on the NiTi Brush package

Expiry date] 5 years from manufactured date.

NiTi brush for peri-implantitis is “Non-sterile” products. Sterile must be done before use.

For more information, please refer to the information for use.

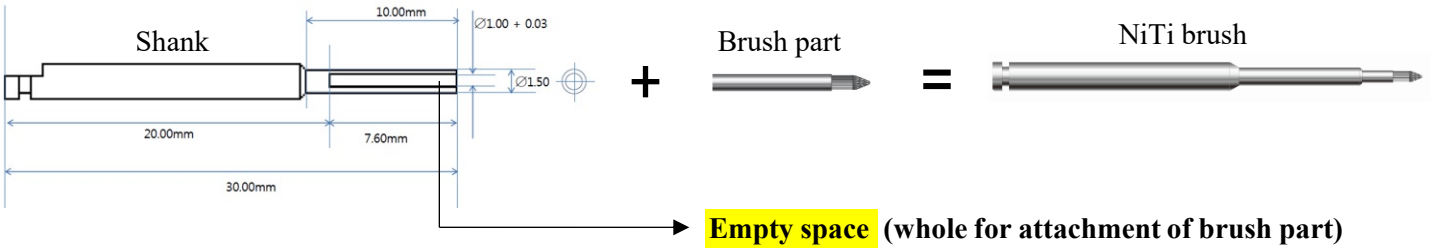
Prepare NiTi Brush | Open the outer box | Pick up the inner box | Open the inner box | Pick up the ICT

Prepare the sterilization | Sterilization 134 ℃ / 15minutes | Insert the NiTi Brush to handpiece | Ready for use

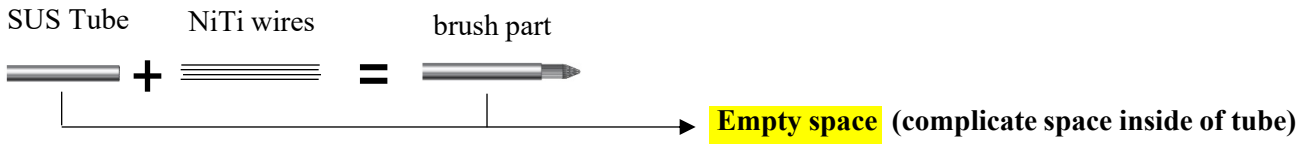
NiTi brush = shank + brush part

Disposable - Single time use only !!!

Shank has long whole has for attachment of brush.



Brush part = SUS tube + NiTi wires



During operation, if a biological material come into the empty space of shank or tube, we do not have any mechanical solution for removing the biological material from the “Long, empty and complicated space”.

◆ **PICTOGRAM**

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	MANUFACTURER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	BATCH CODE (LOT NO.)		CATALOGUE NUMBER (MODEL NAME)
	CAUTION		CONSULT INSTRUCTIONS FOR USE
	DATE OF MANUFACTURE		DO NOT REUSE
	NON STERILE		USE-BY DATE
	KEEP AWAY FROM SUNLIGHT		KEEY DRY
	WEEE		

Manufacturer;	EC Representative;
HANS KOREA CO., LTD. 82-5, MUNWON-GIL, ILSANDONG-GU, GOYANG-SI, GYEONGGI-DO 10254 KOREA [Tel] : +82-31-977-2809 [Fax] : +82-31-976-2809	**OBELIS S.A.** Bd. Général Wahis, 53, 1030 Brussels, Belgium Tel : +32 2 732 59 54, Contact Person: Szymon Nowak-Rogozinski

◆ **Document No.: HKIFU-001**

◆ **Revision date: 2017.07.31 (Rev. 1)**

Key-point of Information for use

Consider before use

- Remove the crown?
- Flap open?
- Operation place?
- Selection of brushes.

- Suggested brush.
- - Flap open , Anterior : Pocket
- - Flap open, Molor : Micro
- - Non flap : Nano

Sterile & Operation

- Non-sterile product.
- Sterile condition :134℃, 15minutes
- Low-speed handpiece(20:1) : (Speed) rpm 600 ~1,200
- Enough irrigation.
- Citric acid or(and) Tetracycline treatment after brushing

After use

- Disposable.
- One patient use only.
- Must dispose after use.
- (Refer page 25)

Articles for Biocompatibility of NiTi as the dental purpose.

In vivo biocompatibility evaluation of nickel-titanium shape memory metal alloy: Muscle and perineural tissue responses and encapsule membrane thickness
http://onlinelibrary.wiley.com/doi/10.1002/(SICI)1097-4636(19980905)41:3%3C481::AID-JBM19%3E3.0.CO;2-L/full

In vivo histological evaluation of bioactive NiTi alloy after two years implantation
http://www.sciencedirect.com/science/article/pii/S0928493106000300?via%3Dihub

Comparative in vitro biocompatibility of nickel-titanium, pure nickel, pure titanium, and stainless steel: genotoxicity and atomic absorption evaluation
https://www.ncbi.nlm.nih.gov/pubmed/10436848

On the nature of the biocompatibility and on medical applications of NiTi shape memory and superelastic alloys
http://content.iospress.com/articles/bio-medical-materials-and-engineering/bme6-4-05

Porous NiTi for bone implants: A review
https://www.researchgate.net/publication/5503397_Porous_NiTi_for_bone_implants_A_review

Biocompatibility evaluation of NickelTitanium shape memory metal alloy
http://jultika.oulu.fi/files/isbn9514252217.pdf

Publications related with NiTi brush for peri-implantitis

Atlas of Oral and Maxillofacial Surgery 1st Edition(Chapter 25)
Authors: Deepak Kademani, Paul Tiwana
Hardcover ISBN: 978-1-4557-5328-4
eBook ISBN: 978-1-4557-5327-7

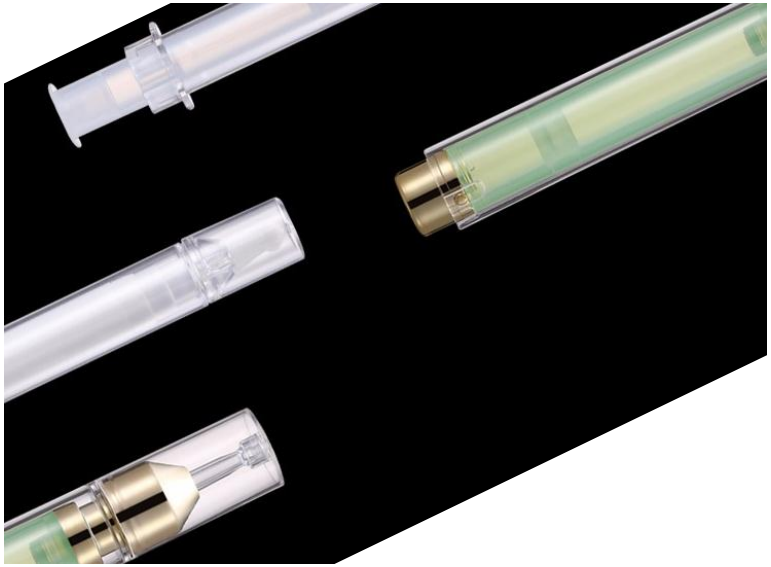
Cementation in Dental Implantology: An Evidence-Based Guide(Chapter 11)
Editor : Chandur P.K Wadhwani
Hardcover ISBN : 978-3-642-55162-8
eBook ISBN : 987-3-624-55163-5

Regeneration of deep peri-implantitis induced bony defect – Mario Roccuzzo

Altered bacterial adhesion with changes in roughness of titanium surfaces after implant cleaning
Seul-Kee Kim, Jae-Kwan Lee, Se Hwan Park, Beom-Seok Chang, Si Young Lee, and Heung-Sik Um

Comparison of mechanical debridement effect for implant surface with treatment alternatives
A. Suzuki, M. Munakata, N. Tachikawa, T. Miyahara, K. Ykawa, K. Fuchigami, M. Sanda, M. Htet, T. Fuzimori, S. Kasugai

Conserva, E.; Bandieri, A.; Bellini, P.; Generali, L.; Sabbadini, L.; Agnini, A.; Consolo, U. (2016) - **Effects of titanium brushes on different implant surfaces: an in vivo investigation** (XXII Congresso Nazionale Collegio dei Docenti Universitari di Discipline Odontostomatologiche - Roma - 14-16 aprile 2016) - MINERVA STOMATOLOGICA - n. volume 65 - pp. da 103 a 104 ISSN: 0026-4970



Special powder for implant surface debridement in peri-implantitis will be followed…….

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What is now proved was once only imagined.

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