





## Process ..... 3

# Product descriptions 4

| 13<br>13<br>14<br>14 |
|----------------------|
| 14<br>14<br>20       |
| 14                   |
| 20                   |
|                      |
|                      |
|                      |
|                      |
| 20                   |
| 21                   |
| 21                   |
| 22                   |
|                      |
|                      |
| 24                   |
|                      |

# Instructions for use ..... 26

# NANO's Three Core Values





Specialist in manufacturing with more than 15 years of experience.



Sterilization

Manufacturing

Environment

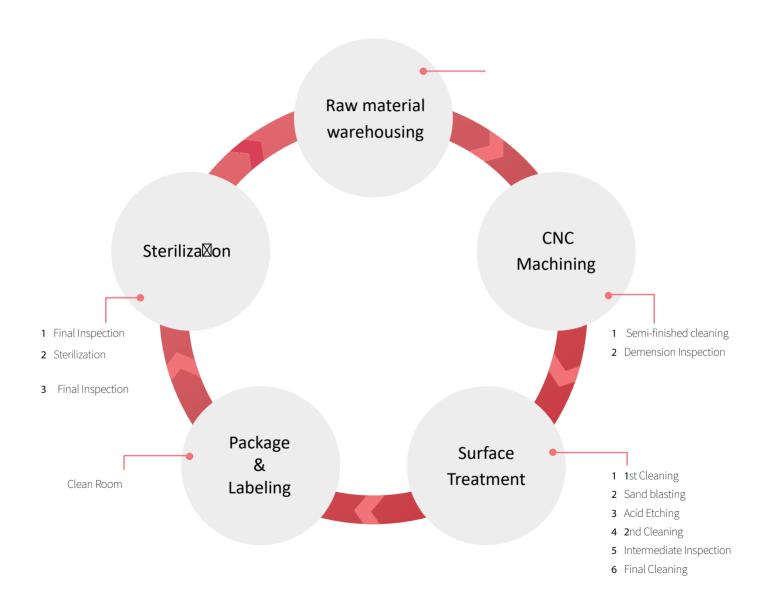
NANO have a rigorous sterile manufacturing environment.



Thorough hygiene management

NANO defend all equipment against germs.

# **NANO** Process





# NANO SLA Sub Fixture

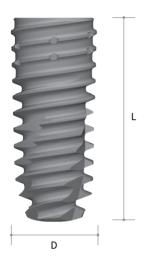


# NANO SLA Sub Fixture

- · 11 degree morse taper & 2.5 internal hex connection
- · Optimal surface shape implementation with acid treatment
  - Optimal surface roughness: Ra 3.0  $\sim$  2.5  $\mu m$
- · Reduce cooling time with the 'Taper body' effect, which is highly entry-friendly
- · Easy to adjust the depth of the plate
- · Self tapping and aggressive threads
- · Plarform Switching for preserving bone
- · Manufactured using pure Titanium (Grade 4)

# **NANO SLA Sub Fixture**







### Diameter Ø 3.5 Length Product Code 7.0 8.5 DSSDR37088S DSSDR37089S 10.0 11.5 DSSDR37081S DSSDR37082S

13.5

| Length | Product Code         |
|--------|----------------------|
| 7.0    | DSSDR <b>37091</b> S |
| 8.5    | DSSDR <b>37092</b> S |
| 10.0   | DSSDR <b>37083</b> S |
| 11.5   | DSSDR <b>37094</b> S |
| 13.5   | DSSDR <b>37095</b> S |
|        |                      |

Diameter ∅4.5

| Length | Product Code         |
|--------|----------------------|
| 7.0    | DSSDR <b>37083</b> S |
| 8.5    | DSSDR <b>37084</b> S |
| 10.0   | DSSDR <b>37085</b> S |
| 11.5   | DSSDR <b>37086</b> S |
| 13.5   | DSSDR <b>37087</b> S |

Diameter ∅ 4.0

| Length | Product Code         |
|--------|----------------------|
| 7.0    | DSSDR <b>37096</b> S |
| 8.5    | DSSDR <b>37002</b> S |
| 10.0   | DSSDR <b>37003</b> S |
| 11.5   | DSSDR <b>37004</b> S |
| 13.5   | DSSDR <b>37005</b> S |

Diameter ∅5.0

Packing Unit Fixture + Cover Screw Driver Hex 2.5 Fixture Driver

Torque 30~40Ncm

## **Cover Screw**





| Fixture Platform | Product Code    |
|------------------|-----------------|
| 3.5              | DSSCR <b>35</b> |
| 4.0 / 4.5/ 5.0   | DSSCR           |

Driver Hex 1.2 Screw Driver

Torque 5~8Ncm

# **Healing Abutment**



| G/H | Product Code |
|-----|--------------|
| 3.0 | DSHR091      |
| 5.0 | DSHR981      |
| 7.0 | DSHR635      |
|     |              |

Diameter Ø/10

| Diameter Ø 5.0 |                 |
|----------------|-----------------|
| G/H            | Product Code    |
| 3.0            | DSHR <b>945</b> |
| 5.0            | DSHR003         |
| 7.0            | DSHR071         |

Packing Unit Abutment

Driver Hex 1.2 Screw Driver

Torque 10Ncm

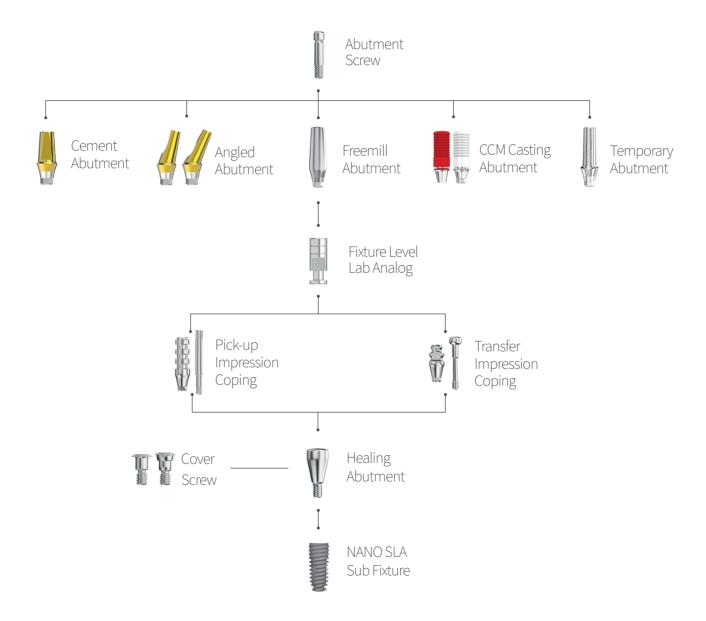
### Diameter ∅4.5

| G/H | Product Code    |
|-----|-----------------|
| 3.0 | DSHR <b>321</b> |
| 5.0 | DSHR <b>334</b> |
| 7.0 | DSHR <b>678</b> |

### Diameter Ø 5.5

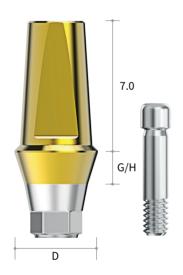
| ž |
|---|
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|   |
|   |
|   |

# Prosthetic Flow Diagram



# **Cement Abutment**





| Diameter ∅4.0 |              |
|---------------|--------------|
| G/H           | Product Code |
| 1.0           | DSCR40107DS  |
| 2.0           | DSCR40207DS  |
| 3.0           | DSCR40307DS  |
| 4.0           | DSCR40407DS  |

| Diameter ∅5.0 |              |
|---------------|--------------|
| G/H           | Product Code |
| 1.0           | DSCR50107DS  |
| 2.0           | DSCR50207DS  |
| 3.0           | DSCR50307DS  |
| 4.0           | DSCR50407DS  |

| Diameter ∅4.5 |              |  |
|---------------|--------------|--|
| G/H           | Product Code |  |
| 1.0           | DSCR45107DS  |  |
| 2.0           | DSCR45207DS  |  |
| 3.0           | DSCR45307DS  |  |
| 4.0           | DSCR45407DS  |  |

| Diameter $\emptyset$ 5.5 |              |
|--------------------------|--------------|
| G/H                      | Product Code |
| 1.0                      | I            |
|                          | DSCR55107DS  |
| 2.0                      | DSCR55207DS  |
| 3.0                      | DSCR55307DS  |
| 4.0                      | DSCR55407DS  |

Packing Unit Abutment + Screw
Driver Hex 1.2 Screw Driver

# **Angled Abutment 15°**





| Diameter ∅4.0 |               |
|---------------|---------------|
| G/H           | Product Code  |
| 1.0           | DSAR401015ADS |
| 2.0           | DSAR402015ADS |
| 3.0           | DSAR403015ADS |
| 4.0           | DSAR404015ADS |

| Diameter Ø 5.0 |               |
|----------------|---------------|
| G/H            | Product Code  |
| 1.0            | DSAR501015ADS |
| 2.0            | DSAR502015ADS |
| 3.0            | DSAR503015ADS |
| 4.0            | DSAR504015ADS |

| Diameter ∅4.5 |               |
|---------------|---------------|
| G/H           | Product Code  |
| 1.0           | DSAR451015ADS |
| 2.0           | DSAR452015ADS |
| 3.0           | DSAR453015ADS |
| 4.0           | DSAR454015ADS |

| Diameter ∅5.5 |               |
|---------------|---------------|
| G/H           | Product Code  |
| 1.0           | <u> </u>      |
|               | DSAR551015ADS |
| 2.0           | DSAR552015ADS |
| 3.0           | DSAR553015ADS |
| 4.0           | DSAR554015ADS |

Packing Unit Abutment + Screw
Driver Hex 1.2 Screw Driver

# **Angled Abutment 25°**





| Diam | Diameter Ø 4.0 |  |
|------|----------------|--|
| G/H  | Product Code   |  |
| 1.0  | DSAR401025ADS  |  |
| 2.0  | DSAR402025ADS  |  |
| 3.0  | DSAR403025ADS  |  |
| 4.0  | DSAR404025ADS  |  |

| Diameter \$25.0 |               |
|-----------------|---------------|
| G/H             | Product Code  |
| 1.0             | DSAR501025ADS |
| 2.0             | DSAR502025ADS |
| 3.0             | DSAR503025ADS |
| 4.0             | DSAR504025ADS |

| Diameter ∅4.5 |               |
|---------------|---------------|
| G/H           | Product Code  |
| 1.0           | DSAR451025ADS |
| 2.0           | DSAR452025ADS |
| 3.0           | DSAR453025ADS |
| 4.0           | DSAR454025ADS |

| Diam | neter Ø 5.5   |
|------|---------------|
| G/H  | Product Code  |
| 1.0  | DSAR551025ADS |
| 2.0  | DSAR552025ADS |
| 3.0  | DSAR553025ADS |
| 4.0  | DSAR554025ADS |

Packing Unit Abutment + Screw
Driver Hex 1.2 Screw Driver

# Freemill Abutment





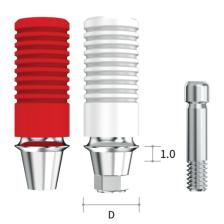
| Diameter $\varnothing$ 4.5 |              |  |
|----------------------------|--------------|--|
|                            | ,            |  |
| G/H                        | Product Code |  |
| 1.0                        | DSMR4510DS   |  |
| 2.0                        | DSMR4520DS   |  |
| 3.0                        | DSMR4530DS   |  |

| Diameter ∅5.5 |              |  |
|---------------|--------------|--|
| G/H           | Product Code |  |
| 1.0           | DSMR5510DS   |  |
| 2.0           | DSMR5520DS   |  |
| 3.0           | DSMR5530DS   |  |

| Diameter ∅5.0 |              |
|---------------|--------------|
|               |              |
| G/H           | Product Code |
| 1.0           | DSMR5010DS   |
| 2.0           | DSMR5020DS   |
| 3.0           | DSMR5030DS   |

Packing Unit Abutment + Screw
Driver Hex 1.2 Screw Driver
Torque 30Ncm

# **CCM Casting Abutment**



| Diameter ∅4.0 |              |
|---------------|--------------|
| Туре          | Product Code |
| Hex           | DCCA4010S    |
| Non Hex       | DCCAN4010S   |

| Туре    | Product Code |
|---------|--------------|
| Hex     | DCCA4510S    |
| Non Hex | DCCAN4510S   |
| Non Hex | DCCAN4510S   |

**Diameter** Ø 4.5

Packing Unit Abutment + Screw
Driver Hex 1.2 Screw Driver
Torque 30Ncm







| Diameter Ø 4.0 |              |  |
|----------------|--------------|--|
|                |              |  |
| G/H            | Product Code |  |
| 1.0            | DST4010DS    |  |

| Diam | neter Ø 4.5  |
|------|--------------|
| G/H  | Product Code |
| 1.0  | DST4510DS    |

Packing Unit Driver

Abutment + Screw Hex 1.2 Screw Driver

**Torque** 20Ncm

# **Fixture Level Lab Analog**



| Length 12    |
|--------------|
|              |
| Product Code |
| DDSLA120     |

Packing Unit Analog

# **Pick-up Impression Coping**





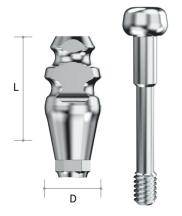
| Length 11 |              |
|-----------|--------------|
| D         | Product Code |
| 4.0       | DPICH4011DS  |
| 4.5       | DPICH4511DS  |
| 5.5       | DPICH5511DS  |

| Length 15 |              |
|-----------|--------------|
| D         | Product Code |
| 4.0       | DPICH4015DS  |
| 4.5       | DPICH4515DS  |
| 5.5       | DPICH5515DS  |

Packing Unit Impression Coping + Guide Pin

**Driver** Hex 1.2 Screw Driver

# **Transfer Impression Coping**



| Length 11 |              |
|-----------|--------------|
| D         | Product Code |
| 4.0       | DTICH4011DS  |
| 4.5       | DTICH4511DS  |
| 5.5       | DTICH5511DS  |

| Length 14 |              |  |
|-----------|--------------|--|
|           |              |  |
| D         | Product Code |  |
| 4.0       | DTICH4014DS  |  |
| 4.5       | DTICH4514DS  |  |
| 5.5       | DTICH5514DS  |  |

Packing Unit Impression Coping + Guide Pin

**Driver** Hex 1.2 Screw Driver



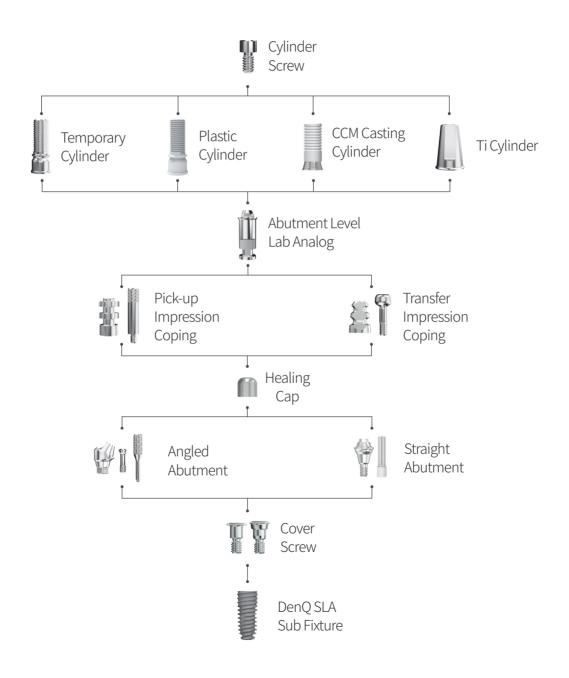
# Multiple Prosthetic System







# **Multiple Prosthetic Flow Diagram**



# **Straight Abutment**



| Diameter ∅4.8 |              |
|---------------|--------------|
| G/H           | Product Code |
| 1.5           | DSMR48152S   |
| 2.5           | DSMR48252S   |
| 3.5           | DSMR48352S   |
| 4.5           | DSMR48452S   |

Packing Unit Abutment + Carrier Driver Internal Hex Driver

Torque 30Ncm

# **Healing Cap**



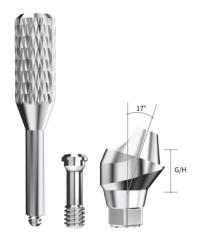
| Diameter ∅4.8 |  |
|---------------|--|
| Product Code  |  |
| MHC48         |  |

Packing Unit Healing Cap

**Driver** Hex 1.2 Screw Driver

# **Angled Abutment 17°**





| <b>Diameter</b> ∅4.8 |               |  |
|----------------------|---------------|--|
| G/H                  | Product Code  |  |
| 2.5                  | DSMAR482517DS |  |
| 3.5                  | DSMAR483517DS |  |

Packing Unit Abutment + Screw + Ti Carrier

**Driver** Hex 1.2 Screw Driver

Torque 30Ncm

# **Angled Abutment 30°**



| <b>Diameter</b> ∅4.8 |               |  |  |  |
|----------------------|---------------|--|--|--|
| G/H                  | Product Code  |  |  |  |
| 3.5                  | DSMAR483530DS |  |  |  |
| 4.5                  | DSMAR484530DS |  |  |  |

Packing Unit Abutment + Screw + Ti Carrier

**Driver** Hex 1.2 Screw Driver

# **CCM Casting Cylinder**



| Diameter ∅4.8 |  |  |
|---------------|--|--|
| Product Code  |  |  |
| MCC480S       |  |  |

Packing Unit Cylinder + Screw
Driver Hex 1.2 Screw Driver

Torque 20Ncm

# **Temporary Cylinder**



| Diameter ∅4.8 |  |  |
|---------------|--|--|
| Product Code  |  |  |
| MTC480S       |  |  |

Packing UnitCylinder + ScrewDriverHex 1.2 Screw Driver

# **Plastic Cylinder**



| Diameter ∅4.8 |  |  |  |  |
|---------------|--|--|--|--|
| Product Code  |  |  |  |  |
| MPC480S       |  |  |  |  |

Packing UnitCylinder + ScrewDriverHex 1.2 Screw Driver

Torque 20Ncm

# Ti Cylinder



| Diameter ∅4.8 |              |  |  |  |
|---------------|--------------|--|--|--|
|               | Product Code |  |  |  |
|               | 1            |  |  |  |
| 7.0           | MTCS487S     |  |  |  |

Packing Unit Cylinder + Screw
Driver Hex 1.2 Screw Driver

# **Abutment Level Lab Analog**



Product Code DMLA480

Packing Unit Analog

# **Pick-up Impression Coping**



Product Code
MPIC480S

Packing Unit Driver

Impression Coping + Guide Pin Hex 1.2 Screw Driver

# **Transfer Impression Coping**



| Diameter ∅4.8 |  |  |  |
|---------------|--|--|--|
| Product Code  |  |  |  |
| MTIC480S      |  |  |  |

Packing Unit Impression Coping + Guide Pin

Driver Hex 1.2 Screw Driver



# NANO Overdenture System



# **Snap-On Ball Abutment**



| G/H | Product Code |  |  |
|-----|--------------|--|--|
| 1.0 | SOBA10       |  |  |
| 2.0 | SOBA20       |  |  |
| 3.0 | SOBA30       |  |  |
| 4.0 | SOBA40       |  |  |
| 5.0 | SOBA50       |  |  |
| 6.0 | SOBA60       |  |  |

Packing Unit Abutment Driver 30Ncm

# **Snap-On Lock Abutment**



| G/H | Product Code |  |
|-----|--------------|--|
| 1.0 | SOLA10       |  |
| 2.0 | SOLA20       |  |
| 3.0 | SOLA30       |  |
| 4.0 | SOLA40       |  |
| 5.0 | SOLA50       |  |
| 6.0 | SOLA60       |  |
| 7.0 | SOLA70       |  |

Packing Unit Abutment Driver 30Ncm



# NANO Instructions For Use

- ·NANO SLA Sub Fixture IFU
- ·NANO Abutment IFU



# NANO SLA Sub Fixture IFU

### 1. Device Description

This product has as dental implant fixture of submerged type to support and maintain the denture by implanting the fixture into the low jaw and upper jaw and restoring it when partially or full edentulous missing natural tooth. It has physical and chemical surface treatment and has a rough and large surface area. The body structure of this dental implant is composed of tapered and tapered-straight structures, and is mechanically connected to the submerged type dental implant abutment upper structure.

### 2.Indications for use

The DenQ Sub SLA 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 dedicated for one and two stage surgical procedures. This system is intended for delayed loading.

### 3. Before use preparing

- (1) The practitioner first checks the patient's oral condition and then makes a decision on the procedure after grasping the patient's problem in detail through diagnosis such as radiographs and models. At this time, the medical evaluation for implant treatment is generally consistent with the points that should be considered during extraction or periodontal surgery by oral surgeons, and there are cases in which systemic health is not good, so be sure to check the patient's medical history before the procedure. In addition, if the patient has a disease that is not aware of, if any doubt arises, necessary clinical tests must be performed before the procedure. If there is no abnormality as a result of the clinical test, fixation is started.
- (2) If necessary prior to the procedure, toothbrushing and oral cleaning procedures and prophylactic antibiotics are given.
- (3) The procedure must be performed by a person skilled or dentist in the procedure, and the procedure must be performed under conditions that can maintain aseptic conditions according to the hospital protocol.
- (4) Before using the product, check the packaging status and expiration date of the product, then open the product, and use it for treatment after checking for any damage or abnormality in the product.
- (5) All surgical instruments used must be sterilized in advance, and sterile gloves, sterile surgical clothing, and sterile consumable must be used



### 4. How to use

- (1) After sterilization the surgical site and performing local anesthesia, the alveolar bone is exposed by raising the mucous valve along the alveolar ridge of the extracted area.
- (2) Set the depth and position of the drill in accordance with the depth of the implant fixture at the site to be placed, designate the placement position with a point drill or a linder man drill on the handpiece, and form the first hole with a drill, counter sink, and tap drill.
- (3) Remove the external sterilization wrapper, open the ampoule lid, fasten the no-mount driver to the handpiece, connect it to the implant fixture, and take care not to be separated or contaminated with foreign substances. The implant fixture is slowly placed. (If it is not possible to place it with the engine, use a ratchet wrench to finish the final placement.) At this time, the recommended torque for the final placement is 30~40Ncm.

- (4) Implant fixture Take out the cover screw inside the ampoule lid, fasten it with a force of 5~8 Ncm to the upper part of the fixture, and seal the gums. If this is small, insert it to protect the connection of the exposed implant fixture.
- (5) Depending on the bone quality, the healing period before connecting the abutment should be at least 3 months for the mandible and 6 months for the upper jaw.

### 5. After using management

- (1) If the operator determines that sufficient bone fusion has been secured, he or she must enter the stage for prosthesis fabrication.
- (2) Since the identification tag with the model name, size, and serial number (lot. no) recorded on the packaging box is attached to the patient chart, X-ray film, etc., product tracking must be possible.
- (3) The operator must check the patient's bone fusion status through X-rays or percussion methods.
- (4) This product is a disposable medical device and reuse is prohibited.



### 6. Precautions for use

- Warning
- 1) Implants are not reused and must be applied according to the purpose of use and the area of use.
- 2) Since the surgical procedure to place the implant fixture is a very specialized and complex procedure, specialized training is recommended.
- 3) Damaged or mishandled implants must be removed.
- 4) The operating room should be kept sterile and should be performed after wearing sterile surgical clothing.
- 5) Defective products must be returned.
- 6) Superstructure with inappropriate and excessive angles should not be used.

- 7) Appropriate and appropriate surgical instruments, surgical kits and surgical engines should be used.
- 8) Excessive drilling and torque can damage and harm the fixture and surgical site.
- 9) Small diameter implant and angled abutments are not recommended for the posterior region of the mouth.
- 10) The NANOSub Implant System and Abutments have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the NANO Sub Implant System and Abutments in the MR environment is unknown. Scanning a patient who has one of these devices may result in patient injury.



### 7. Contraindication

Procedures should be considered as below

### Oral contraindications

- 1 Iveolar bone pathology
- 2 Radiation treatment on jaw bone
- 3 Dry mouth
- 4 Hypertrophy of tongue
- (Vitiligo, lichen planus, stomatitis)
- **6** Bad oral hygiene

# Temporarily limited contraindications

- ① Acute inflammatory diseases and infection
- ② Pregnancy
- (anticoagulant, immunosuppressant)
- 4 Physical and mental stress status

### Mental

### contraindications

- 1) Patients with poor cooperation
- 2 Alcohol and drug abuse
- 3 Neurotic and psychotic patients
- 4 Problem patient

# General medical contraindications

- ① Current drug use (corticosteroid, long-term antibiotic treatment)
- 2 Metabolic disorders (adolescent diabetes, diabetes level 300 or higher)
- $\begin{tabular}{ll} \hline \end{tabular} \begin{tabular}{ll} \hline \end{$
- 4 Heart and circulatory disorders (arteriosclerosis, high blood pressure level over 300)



### 8. Side effect

- If the width and height of the alveolar bone surrounding the implant fixture is insufficient, it may cause failure when placing the implant fixture.
- (1) The implant procedure has risks such as local swelling, skin weakness, swelling, hematoma, and bleeding, and the lower lip and jaw may be paralyzed during the mandibular procedure, and in the case of the maxilla, the tissue next to the nose may be paralyzed.

### 9. General precautions

- (1) If you have bone disease (osteoporosis, osteomalacia), or bone metabolism disorder, you should carefully consider this before the procedure.
- (2) Bone fusion may fail due to infection, mobility or bone loss. Failed implants should be removed as soon as possible, and all granular tissue should be removed from the implant fixture placement site.
- (3) Bone suitability should be determined through visual inspection of the photo of the room letter, palpation and the proposed implant fixture position.
- (4) This implant is a sterilized product, and sterilization cannot be guaranteed if the package is opened or damaged.
- (5) After completion of treatment, the patient is checked for the treatment site through periodic checks.

### 10. Application precautions

- (1) The maxillary must have a healing period of 6 to 8 months depending on the bone quality, and the mandible must have a healing period of 3 to 5 months depending on the bone quality.
- (2) During the healing period, if pressure such as masticatory pressure is applied to the implant fixture, initial fixation may not be obtained, or bone fusion may not be possible with the implant fixture during the healing period. Therefore, after the implant fixture is placed, it takes time for the bone tissue to heal until the upper prosthesis is installed. Therefore, the occlusal force should not be applied to the implanted area, and the patient should be sufficiently informed not to drink or smoke, which interferes with the healing process.

### 11. Storage condition

Room temperature

### 12. Removal procedure

When removing fixture, disconnect upper prosthesis first, which is directly connected to fixture and then connect the surgical equipment and driver inside the connection of installed fixture to turn anticlockwise.



### 13. Foreign Language Manual Support

This manual is basically written in Korean and English. When exported to other countries, the contents will be translated into a relevant language to be provided with the manual.

- (1) The manual to be translated into a language of importing country by NANO
- (2) The manual in English and the one in #1) to be sent to the company in importing country for confirmation. Revision to be reflected on the final version.
- (3) The basic manual both in Korean & English and #2) to be packaged together.

Caution: Federal law restricts this device to sale by or on their order of a licensed dentist.



### 14. Symbols



Caution



Electronic instruction for use



Manufacturer



Catalogue number



Batch code/Lot. No.



Date of manufacture



Do not re-use



Do not resterilize



Use-by date



Sterilized using irradiation



Temperature limit



Caution: U.S. Federal law restricts these devices for sale, distribution and use by, or on the order of a dentist or physician



Do not use if package is damaged



CE mark



EU Authoriosed Representative



### 1. Device Description

This product has as dental implant fixture of submerged type to support and maintain the denture by implanting the fixture into the low jaw and upper jaw and restoring it when partially or full edentulous missing natural tooth. It has physical and chemical surface treatment and has a rough and large surface area. The body structure of this dental implant is composed of tapered and tapered-straight structures, and is mechanically connected to the submerged type dental implant abutment upper structure.

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- (2) If necessary prior to the procedure, toothbrushing and oral cleaning procedures and prophylactic antibiotics are given.
- (3) The procedure must be performed by a person skilled or dentist in the procedure, and the procedure must be performed under conditions that can maintain aseptic conditions according to the hospital protocol.
- (4) Before using the product, check the packaging status and expiration date of the product, then open the product, and use it for treatment after checking for any damage or abnormality in the product.
- (5) All surgical instruments used must be sterilized in advance, and sterile gloves, sterile surgical clothing, and sterile consumable must be used.
- (6) The dental abutment must be sterilized under the conditions presented before use, and must be dried and operated with sterile instruments or gloves.



### 4. Sterilization condition

Dental Abutment should be sterilized as below before use.

| Туре       | Temperature    | Expose time | Pressure           | Dry time   |
|------------|----------------|-------------|--------------------|------------|
| Gravity    | 132°C<br>270°F | 40 mins     | 1 bars<br>14.5 psi | 30 minutes |
| Pre-vacuum | 132°C<br>270°F | 3 mins      | 2 bars<br>28.5 psi | 30 minutes |





### 5. How to use

- 5.1 Impression of fixture level
- (1) After confirming that the osseointergration of dental implant fixture was successful, select a dental abutment suitable for the adjacent teeth and the dental environment.
- (2) Remove the healing abutment and fasten the pick up impression coping to the dental fixture with picker torque(10 Ncm or less)
- (3) Fill impression tray with an impression agent, inject the impression material around the impression coping and take an impression.
- (4) The obtained tray is sent to the dental laboratory to fabricate a prosthesis, and the patient fastens the healing abutment and returns it.
- (5) When the prosthesis is completed, the healing abutment in the patient's mouth is removed and the selected abutment is fastened. At the time, tighten with the same torque three times every 5 minutes after the initial torque.
- (6) Appropriate cement is embedded in the manufactured prosthesis and bonded to the oral abutment, and residual cement is removed.
- (7) Adjust occlusion with adjacent and opposing teeth and complete treatment.

- 5.2 Impression of abutment level
- (1) After confirming that the osseointergration of dental implant fixture was successful, select a dental abutment suitable for the adjacent teeth and the dental environment.
- (2) Remove the healing abutment and tighten the selected abutment with the recommended torque.
- (3) Fasten the impression cap and impression to the abutment, fill the tray with impression material, and take an impression.
- (4) The obtained tray is sent to the dental laboratory to make prosthesis, and the patient fastens the protective cap and returns it.
- (5) When the prosthesis is completed, appropriate cement is embedded and bonded to the oral abutment, and residual cement is removed.
- (6) Adjust occlusion with adjacent and opposing teeth and complete treatment.



### 6. After using management

- (1) Since the identification tag with the model name, size, and serial number (lot. no) recorded on the packaging box is attached to the patient chart, X-ray film, etc., product tracking must be possible.
- (2) The operator must check the patient's bone fusion status through X-rays or percussion methods.
- (3) This product is a disposable medical device and reuse is prohibited.

### 7. Precautions for use

- (1) Warning
- (1) Implants are not reused and must be applied according to the purpose of use and the area of use.
- (2) Since the surgical procedure to place the implant abutment is a very specialized and complex procedure, specialized training is recommended.
- (3) Damaged or mishandled implants must be removed.
- (4) The operating room should be kept sterile and should be performed after wearing sterile surgical clothing.
- (5) Defective products must be returned.
- (6) Small diameter implant and angled abutments are not recommended for the posterior region of the mouth.
- (7) The DenQ Sub Implant System and Abutments have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the DenQ Sub Implant System and Abutments in the MR environment is unknown. Scanning a patient who has one of these devices may result in patient injury.



### (2) Contraindication

Procedures should be considered as below

### Oral contraindications

- 1 Iveolar bone pathology
- 2 Radiation treatment on jaw bone
- 3 Dry mouth
- 4 Hypertrophy of tongue
- (Vitiligo, lichen planus, stomatitis)
- 6 Bad oral hygiene

# Temporarily limited contraindications

- 1 Acute inflammatory diseases and infection
- 2 Pregnancy
- ③ Temporary use of certain drug (anticoagulant, immunosuppressant)
- 4 Physical and mental stress status

### Mental

### contraindications

- 1) Patients with poor cooperation
- 2 Alcohol and drug abuse
- 3 Neurotic and psychotic patients
- 4 Problem patient

# General medical contraindications

- ① Current drug use(corticosteroid, long-term antibiotic treatment)
- 2 Metabolic disorders(adolescent diabetes, diabetes level 300 or higher)
- 3 Hematologic disorder(red blood cells, white blood cells, blood clotting system disorders
- 4 Heart and circulatory disorders(arteriosclerosis, high blood pressure level over 300)



### 8. Side effect

- (1) The dental abutment may cause bone resorption around the implant due to excessive occlusion or improper occlusion setting.
- (2) Since dental abutment may be partially subsided by adjacent and opposing teeth, proper occlusion setting is required, and periodic recall check and re-torque are required.
- (3) The implant procedure has risks such as local swelling, skin weakness, swelling, hematoma, and bleeding, and the lower lip and jaw may be paralyzed during the mandibular procedure, and in the case of the maxilla, the tissue next to the nose may be paralyzed.

### 9. General precautions

- (1) If you have bone disease (osteoporosis, osteomalacia), or bone metabolism disorder, you should carefully consider this before the procedure.
- (2) Bone fusion may fail due to infection, mobility or bone loss. Failed implants should be removed as soon as possible, and all granular tissue should be removed from the implant fixture placement site.
- (3) This implant abutment should be used after sterilization according to the recommended conditions before use.
- (4) After completion of treatment, the patient is checked for the treatment site through periodic checks.

### 10. Application precautions

- (1) The maxillary must have a healing period of 6 to 8 months depending on the bone quality, and the mandible must have a healing period of 3 to 5 months depending on the bone quality.
- (2) During the healing period, if pressure such as masticatory pressure is applied to the implant fixture, initial fixation may not be obtained, or bone fusion may not be possible with the implant fixture during the healing period. Therefore, after the implant fixture is placed, it takes time for the bone tissue to heal until the upper prosthesis is installed. Therefore, the occlusal force should not be applied to the implanted area, and the patient should be sufficiently informed not to drink or smoke, which interferes with the healing process.



### 11. Storage condition

Room temperature

### 12. Removal procedure

When removing fixture, disconnect upper prosthesis first, which is directly connected to fixture and then connect the surgical equipment and driver inside the connection of installed fixture to turn anticlockwise.

### 13. Foreign Language Manual Support

This manual is basically written in Korean and English. When exported to other countries, the contents will be translated into a relevant language to be provided with the manual.

- (1) The manual to be translated into a language of importing country by DenQ.
- (2) The manual in English and the one in \(\mathbb{H}\)) to be sent to the company in importing country for confirmation. Revision to be reflected on the final version.
- (3) The basic manual both in Korean & English and  $\Gamma$ #) to be packaged together.

Caution: Federal law restricts this device to sale by or on their order of a licensed dentist.





### 14. Symbols



Caution



Electronic instruction for use



Manufacturer



Catalogue number



Batch code/Lot. No.



Date of manufacture



Non-sterile



Temperature limit



Caution: U.S. Federal law restricts these devices for sale, distribution and use by, or on the order of a dentist or physician



Do not use if package is damaged



CE mark



EU Authoriosed Representative



Do not re-use



