Instructions for Use
NB Mini Implant System

Caution: *U.S. federal law restricts this device to sale by or on the order of a dental professional.*

Indications for Use

The NB Mini Implant System is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The NB Mini Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

The Fixture has below featured:

Name	Uses	Surface
NB Fixture Mini	NB Fixture Mini is placed directly into the bone beneath the gumline. The implant fixture is essentially serve as the new roots for the prosthetic tooth.	SLA

The Abutments have below featured:

Name	Uses	Surface
Cover Screw	The Cover Screw is intended to be temporarily connected to an endosseous dental implant to protect the implant connection interface during bone healing.	N/A
Healing Abutment	The Healing Abutment is designed to aid in soft tissue contouring during the healing period after implant placement, creating an emergence profile for the final prosthesis.	N/A
Scan Healing Abutment	The Scan Healing Abutment has the added feature of machined markings for easy identification when taking an abutment-level impression or an intraoral scan/digital impression from the healing abutment. Identification and orientation information is captured in the intraoral scan or model scan.	N/A
Scan Healing Abutment Screw	The Scan Healing Abutment Screw is used for connect fixture and Scan Healing abutment.	N/A
Cemented Abutment Mini	The Cemented Abutment Mini is used as a support of prosthesis to restore the patient's chewing function.	TiN Coating
Angled Abutment Mini	The Angled Abutment Mini is used as a support of prosthesis to restore the patient's chewing function.	TiN Coating
Abutment Screw	The Abutment Screw is used for connect fixture and abutment.	N/A

NB Fixture Mini, Cover Screw, Healing Abutment and Scan Healing Abutment are provided sterilized. And the other Abutments are provided non-sterilized.

NB Fixture Mini is enclosed with Cover Screw in a packing.

Cemented Abutment and Angled Abutment are enclosed with Abutment Screw in a packing.

Device Description

The NB Mini Implant System is composed of NB Fixture Mini, Cover Screw, Healing Abutment, Scan Healing Abutment, Cemented Abutment Mini and Angled Abutment Mini.

Fixture's surface is treated with SLA (Sandblasted with Large-grit and Acid-etching). It is only part to be implanted into bone, and to provide connection of prosthetic devices or other components of a dental implant set with human body (mandibular or maxillary bone).

An endosseous dental implant is a device made of a material such as Ti-6Al-4V Eli (Conforming to ASTM F136) which will be placed in the alveolar bone to replace the function of the missing tooth. The NB Mini Implant System consists of dental implants, abutments for use in one or two-stage dental implant placement and restorations. The implant-abutment connection is tight and precise fitting with internal hex and morse taper bevel.

Contraindications

1) Patient with a serious medical disease (diabetes, hypertensive and more)
2) Patients who have received radiation treatment for a malignant tumor
3) Patients who have problems in jaw relation and occlusion
4) Patient concerning the acute inflammatory disease (Inappropriate oral condition etc.)
5) Pregnant
6) Smoker, Weak mental patient such an alcoholic, drug abuse and neurotic
7) Blood coagulation defect or serious cardiac disorder patient
8) Allergic to Titanium
9) Inoperable patient

Warnings and Precautions

Clinician judgment, as related to individual patient presentations, must always supersede recommendations in any ARUM DENTISTRY Instructions for Use (IFU). Clinicians are responsible for understanding the appropriate technical use of ARUM DENTISTRY prosthetic components. Additional technical information is available upon request from ARUM DENTISTRY, or may be viewed and/or downloaded at 'https://www.arumdentistry.com'.

Contact ARUM DENTISTRY or your local representative with any questions you have regarding specific IFU.

Dental implants can break in function for a number of reasons including overloading due to improper occlusion, metal fatigue, and over-tightening of the implant during insertion. Potential causes of abutment fracture include, but are not limited to: inadequate implant support when attached to period ontically compromised teeth, non-passive fit of superstructure, overloading due to improper occlusion, incomplete seating of cemented abutments, and excessive cantilevering of pontics.

If any modifications are made to the implant/abutment interface, the abutment may not properly engage with the implant fixture.

Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.

Prosthetics are single patient use only. To eliminate the risk of cross-patient contamination,

re-use of the Abutment should not be attempted. ARUM DENTISTRY assumes no responsibility for attempted re-use or re-sterilization between patients.

The Angled abutments are intended to be placed on implant bodies angled at 17 degrees. The Angled Abutment should not be positioned beyond 17°. Implants placed at severe angles relative to existing implants can result in overloading of implants

Caution

1) Carefully consider the patient's condition who has bone diseases (Osteoporosis, Osteomalacia) or bone metabolic disorder in advance.
2) Implants with a diameter of less than 4.5 mm and angled abutments are not recommended to use the posterior teeth (risk of fracture).
3) Small diameter implant and angled abutments are not recommended for use in the posterior region of the mouth.

How to Use

[Before the surgery]

1) Select the appropriate size of an implant after checking the oral condition of the patient.

2) Check whether the surgical instruments and tools are sterilized properly and ready for the surgery to follow the surgery plan.

< 1st Stage Surgery>

1) Check the implant placement position. Consider the height of the bone adjacent to the implant contact surface or the distance between the neighboring implants, and location of nerve of a tooth.

2) After disinfection of oral, make an incision on the gingiva where the implant is going to be placed.

3) Conduct 1 ~ 5 mm drilling on the cortical bone with the Point Drill.

4) Conduct enough drilling for the implant placement with the appropriate to the Initial drill. (Recommended speed: 1,200 rpm) * Since the drill is up to 1mm longer than the implant, the length must be considered when placing it. * Enough irrigation should be conducted during the drilling process in order to minimize the bone damage that occurred due to bone heating.

5) After drilling, check the drilling depth and condition using the Depth Gauge.

6) Use a Parallel Pin to determine the appropriate location and direction of the hole. And then, check the occlusal relationship with the antagonist. * If the placement direction is not correct, correct the direction using a Point drill.

7) Choose an appropriate size of Drill depending on the fixture diameter and then drill fully. * When the bone density is D4, conduct drilling only before two steps of the final Drill, and when it is D3, drilling only up to the previous step of the final Drill, and when it is D1 or D2, drill up to the final Drill. (Refer to the catalogs and brochures for the detailed surgical protocols.) * For wide fixtures, use a tap drill on the D1 or D2 bone.

8) Open the sterilized package after checking the type, size, and expiration date of the implant specified on the label and packaging status.

9) Connect the Fixture Driver mounted on the Hand Piece or Torque Ratchet to the implant in a straight line. * Check the hex direction of the fixture and fixture driver for perfect connect.

10) Be careful to prevent contamination of implants from metal or saliva. Fully insert the implant inside the bone with the torque value of 35 ~ 45 N·cm by placing the implant in the pre-drilled

hole and rotate the Hand Piece with 25~35 rpm. * Make sure not to exceed 50 N·cm when placing an implant.

11) Remove the Fixture Driver by slight lift. * When placing the implants using the Torque Ratchet or Fixture Driver, make sure not to apply excessive force. It may cause necrosis and various types of defects as the bone has been excessively compressed. When you feel strong resistance (around 50 N·cm), remove the implant by rotating it, and then drill larger.

12) According to the operator's decision, connect the Cover Screw or Healing Abutment with 8 ~ 10 N·cm, and suture the soft tissue.

<2nd Stage Surgery>

1) Expose the Cover Screw making an incision on the soft tissue placed on the placed area, after alveolar mucosa is healed and osseointegration is done.
2) Remove the Cover Screw and connect the Healing Abutment.
3) Non-sterile conditions, so the product to be sterilized with moist heat sterilization using the gravity displacement autoclave for 30 minutes at temperatures 121 °C (250 °F) and pressure of 4bar (±10 %), and to be dried for 20 minutes or pre-vacuum displacement for 4 minutes at temperature 132 °C (270 °F), FDA-cleared accessories (e.g. pouch, wrap, tray) are to be used during the sterilization of the prosthetic components.
4) Suture the soft tissue around the Healing Abutment.

<3th Stage Surgery>

1) When attaching the prosthesis in the patient's mouth after the operator must check the fixture and condition of the patient's teeth with X-ray pictures and percussion reaction, the treatment should be performed.
2) Make a dental technical model based on the impression techniques and fabricate or choice the prosthesis considering occlusion, intensity, and aesthetics.
3) Non-sterile conditions, so the product to be sterilized with moist heat sterilization using the gravity displacement autoclave for 30 minutes at temperatures 121°C (250 °F) and pressure of 4bar (±10 %), and to be dried for 20 minutes or pre-vacuum displacement for 4 minutes at temperature 132°C (270 °F), FDA cleared accessories (e.g. pouch, wrap, tray) are to be used during the sterilization of the prosthetic components. 4) After placing an implant, connect the Cover Screw or Healing Abutment with 8 ~ 10 N·cm.
5) Remove Cover Screw or Healing Abutment, connect the Abutment, Abutment Screw is complied with the recommended torque (25 N·cm) when signing.
6) It is thoroughly cleaned to eliminate any residual impurities after signing.
7) Finish the surgery after installing the prosthesis.
8) Do not use other surgical procedure other than for the stated purpose.

Warranty

1) Safety Instructions: Responsibility for proper cleaning, disinfection and sterilization of products is the sole responsibility of the operator / product user.
2) National regulations including limitations must be carefully followed.
3) All our products are designed and manufactured to meet the highest quality demands.
4) The manufacturer of the products excludes any warranty claims and assumes no liability for direct or consequential damage as a result of:

- Misuse
- Improper use, application or handling
- Improper preparation and sterilization
- Improper maintenance and repair
- Failure to observe the Instructions for Use

Adverse Effects

The following complications may occur relative to implant placement: pain, discomfort, dehiscence, delayed healing, paresthesia, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, the need for additional surgery or removal, local and generalized allergic reaction, lack of integration, loss of bone, and loss of implant. Other adverse effects may also occur as a result of iatrogenic factors and host responses.

Single Use

The NB Mini Implant System is for single-use only. Re-use of a single use device that has come in contact with blood, bone, tissue, body fluids or other contaminants may lead to patient or user injury. Possible risks associated with re-use of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

Cleaning and Sterilization

The Cover Screw, Healing Abutment, Scan Healing Abutment and NB Fixture Mini are provided as sterile. The Cemented Abutment Mini, Angled Abutment Mini and the accompanying prosthetic screw are provided as non-sterile, they as a final finished device must be cleaned and sterilized prior to final placement in the restorative site. Always handle the product with powder-free gloves and avoid contact with hard objects that may cause damage to the surface. Device cleaning and sterilization should be performed using the following validated protocols:

Cleaning

Cleaning of the prosthetic components is performed in the dental clinic according to the following parameters:

1. Rinse and brush using a soft-bristled brush under free-flowing tap water.
2. Soak in enzymatic solution in an ultrasonic cleaner for at least 5 minutes following cleaning solution manufacturer's instructions.
3. While submerged in the enzymatic solution, gently brush the device with a soft bristled brush.
4. Rinse under free-flowing distilled water. Completely dry and inspect abutment for integrity and flaws.

Sterilization

Place the final-prepped and cleaned abutment and prosthetic screw in a 510k-cleared sterilization bag and follow ***one*** of the following qualified sterilization cycles in a 510k-cleared sterilizer.

Method	Cycle	Temperature	Exposure time	Drying time
Steam	Pre-Vacuum	132°C (270°F)	4 mins	20 mins
Steam	Gravity	121°C (250°F)	30 mins	20 mins

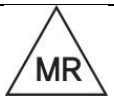
Table 2. Recommended Steam Sterilization Protocols

MR Conditional

The RF Safety of the NB Mini Implant System has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the RF coil. A patient with such a device may be scanned safety after placement under the following conditions:

Device Name	NB Mini Implant System
Static Magnetic Field Strength (B_0)	≤3.0 Tesla
Maximum Spatial Field Gradient	30 T/m (3,000 Gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body Specific Absorption Rate (SAR)	2 W/Kg (Normal Operating Mode)
Maximum Head Specific Absorption Rate (SAR)	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

Label Symbols

Symbol	Description	Symbol	Description
	Catalog Number		Consult Instructions for Use
	Batch Code		Do Not reuse
	Date of Manufacture		Legal Manufacturer
	Caution		Use by Prescription Only
	Use-by date		Sterilized using irradiation
	MR Conditional- Device poses no known hazards in a specified MR environment with specified conditions of use		
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