General Description
An endosseous dental implant is a device made of a material such as Pure titanium (Conforming to ASTM F67) which will be placed in the alveolar bone to replace the function of the missing tooth. 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).
Abutments are fabricated from Ti-6Al-4V Eli of ASTM F136.

Indication for Use
The NB 1 SA 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. NB 1 SA Implant System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. Also, implants with diameters larger than 5mm are indicated for molar regions.

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℃ (250℉) and pressure of 4bar (±10%), and to be dried for 20 minutes or pre-vacuum displacement for 4 minutes at temperature 132℃ (270℉), 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℃ (250℉) and pressure of 4bar (±10%), and to be dried for 20 minutes or pre-vacuum displacement for 4 minutes at temperature 132℃ (270℉), 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 (35 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.

※ **How to sterilize for Abutments**
Place the Product 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 Tim
Steam	Pre-Vacuum	132℃ (270℉)	4 mins	20 mins
Steam	Gravity	121℃ (250℉)	30 mins	20 mins

Warning
Only dentists who have completed the implant education and training may operate. The operator should be fully aware of the manual and precautions of the product, and then select the products according to the treatment plan. Inappropriate patient selection or surgeries may result in implant failure or bone loss around the implant. For the patients with excessive occlusal forces may cause osseointegration failure or fracture of the implant, therefore place the implant that has sufficient thickness, length and make sure to place enough implant in quantity to resist the occlusal force. As the product is sterilized, open and use in a clean environment right before the surgery. Damaged packages should be discarded as the sterilization condition cannot be guaranteed.

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 4.5mm are not recommended to use the posterior teeth (risk of fracture). 3) Implants with bigger than 5mm in diameter, and shorter than 7mm are should be splinted with other restorations during prosthetic treatment. 4) Implants less than 3.5mm should be used only on the anterior teeth.

Contraindication
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

Side effects
1) Complications such as malocclusion, paresthesia caused by neurological damage, infection, edema, hypodermal bleeding, pain, soft tissue ulcer can arise. 2) Loosening of a screw, fracture of prosthetic or implant. 3) Bone defect around the implant and mucositis.

Storage and maintenance
Store at room temperature. 1) Do not reuse the products. (disposable medical

device) 2) Discard any opened products even though they are not used. 3) Discard package of used product. 4) Cleaning or sterile the surgical instrument to use cleaning products, alcohol, distilled water, or other solution.

Disposal
Observe country-specific regulations and laws for the disposal of medical devices. ※ The fixture is provided sterile and intended for a single use. ※ In case of serious accidents, users should inform ARUM DENTISTRY and the authority.

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

MR Statement
The RF safety of the NB 1 SA 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 safely after placement under the following conditions:

Device Name	NB 1 SA 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

REF	Catalog Number		Consult Instructions for Use
LOT	Batch Code		Do Not reuse
	Date of Manufacture	STERILE R	Sterilized using irradiation
	Legal Manufacturer	Rx only	Use by Prescription Only
	Caution		Don't use if package is damaged
30°C 1°C	Temperature limit		Use-by date
MR	MR Conditional- Device poses no known hazards in a specified MR environment with specified conditions of use		
	ARUM DENTISTRY Co., Ltd. 23, Gukjegwahak 11-ro, Yuseong-gu, Daejeon, 34002, Republic of Korea Tel: +82-42-935-3644 Fax: +82-42-935-3633 http://www.arumdentistry.com		