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

Indications for Use
ARUM DENTISTRY’s Customized Abutments are intended for attachment to dental implants in order to provide support for customized prosthetic restorations. Customized Abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. The Customized Abutment will be attached to a dental implant using the included ARUM Dentistry prosthetic screw.
Customized Abutments are compatible with the implant systems listed in the Compatibility Table:

Implant Platform compatibility	Restorative Platform diameter (mm)	Implant Body diameter (mm)
NB 1 SA Implant System	3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5	3.8, 4.0, 4.15, 4.25, 4.5, 5.0

All digitally-designed Customized Abutments are intended to be sent to an ARUM Dentistry-validated milling center for manufacture.

Device Information
The Customized Abutments is a pre-formed titanium cylinder which is customized using CAD/CAM technology to produce a patient-specific customized dental implant abutment. The design of the abutment may be done by a dental laboratory using 510(k)-cleared implant abutment design software. Customized Abutments are to be sent to an ARUM DENTISTRY validated milling center for manufacture.

Contraindications
The Customized Abutment should not be used in patients who have contraindicated systemic or uncontrolled local diseases such as blood dyscrasias, diabetes, hyperthyroidism, oral infections or malignancies, renal disease, uncontrolled hypertension, liver problems, leukemia, severe vascular heart disease, hepatitis, immunosuppressive disorder, pregnancy, collagen and bone diseases. Relative contraindications may include habits such as tobacco use, alcohol consumption, poor oral hygiene, bruxism, nail biting, pencil biting and improper tongue habits depending on severity.

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

The Customized Abutment is not represented to be Pyrogen-free.

Breakage
Implant and abutment fractures can occur when applied loads exceed the normal functional design tolerances of the implant components. Potential overloading conditions may result from significant bone loss (e.g. >3mm), deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing, clenching), loss or changes in dentition or functionality, inadequate prosthesis fit, and physical trauma. Additional treatment may be necessary when any of the above conditions are present to reduce the possibility of breakage.

Changes in Performance
It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

Hygiene and Maintenance
Long-term implant health is directly related to the maintenance of oral hygiene. Potential implant candidates should establish an adequate oral hygiene regimen prior to implant therapy. Following implant placement, the clinician should instruct the patient on proper tools and techniques to ensure long-term maintenance of the implant(s). The patient should also be instructed to maintain routinely scheduled prophylaxis and evaluation appointments.

General Considerations
Control of biomechanical stresses is the key factor to long-term success of the prosthesis. Even after implant integration, imbalances in occlusal forces can lead to implant failure. Implant patients should be monitored post-operatively for screw loosening, peri-implant bone loss and tooth wear as signs of occlusal overloading.

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
Customized Abutment 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.

Product Packaging
Customized Abutment is provided in a sealed polybag. The label on the packaging contains a device part number lot number which should be recorded in the patient’s file to ensure complete traceability of the product.

Included with the Customized Abutment are two screws. One is intended to be used as a laboratory screw for laboratory prosthesis preparation and development processes. The other screw is intended to be used as a prosthetic or clinical screw. The screws are identical and can be used either as a laboratory screw or a prosthetic screw, but not both. Once a screw has been selected for laboratory use, please keep the remaining prosthetic screw separated and protected for clinical use.

Cleaning and Sterilization
The Customized Abutment 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 CAD/CAM 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

Clinical Procedure

Clinical procedure to be carried out in the dental practice, following delivery of the restoration from the dental laboratory.

1. Clean and sterilize the Customized Abutment customized abutment and prosthetic screw according to the above clearing and sterilization parameters.

2. Connect the abutment onto the implant fixture. It is recommended the original implant manufacturers prosthetic tooling and torque are applied to the screw. The abutment should be torqued to 35 N·cm using a driver and Manual Torque Wrench Prosthetic.

3. Once the abutment is inserted into the implant fixture, its seating verified and the defined torque applied, seal the screw access hole of the abutment using conventional procedures. Alternatively, if a final crown/bridge is to be cemented onto the abutment, conventional procedures should be followed.

MR Conditional

The RF Safety of the Customized Abutment 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	Customized Abutment
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

Placement Technique Information

1. Remove the surgical cover screw, healing collar or temporary abutment from the implant fixture using a tool.

2. Place the abutment on the implant fixture. Rotate it sufficiently engaging and ensure seating of the abutment. Once the abutment is in place, tighten the separate retaining screw with a tool.

3. If modifications are needed, mark areas of reduction and remove abutment to perform bulk trimming extra-orally. The abutment removal tool may be necessary to remove the abutment from the implant. Do not modify the abutment implant interface area.

Re-insert abutment to original position and re-evaluate reduction.

4. To achieve optimum torque, tighten the screw to recommended value (Compatibility and Component Table reference) with a calibrated prosthetic torque wrench. Following modification and reattachment, verify with periapical x-rays that the abutment is seated flush onto the implant.

5. Block out the screw access hole with appropriate material.

6. Bond the restoration to the according to the cement manufacturer’s instructions. Use only dental cement/bonding materials suitable for the restoration material to titanium.

Label Symbols

Symbol	Description	Symbol	Description
REF	Catalog Number		Consult Instructions for Use
LOT	Batch Code		Do Not reuse
	Date of Manufacture		Legal Manufacturer
	Caution	Rx only	Use by Prescription Only
1°C ~ 30°C	temperature limit	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, 34002, Daejeon, Republic of Korea
Tel. +82-42-935-3644 Fax. +82-42-935-3633