Instructions For Use (Custom Abutment)

[AD-IFU-001 (Rev. 8.0) 2022.06]

▣ Device description
1) Brand Name : Custom Abutment 2) Device Name : Abutment & Abutment screw
▣ Intended for use
Implant, endosseous, superstructure An abutment of the implant, which is inserted to support a prosthesis like an artificial tooth to be used for restoring the patient's masticatory function.
▣ Raw Material

Device	Material
Abutment	Ti-6Al-4V Eli
Abutment Screw	Ti-6Al-4V Eli

▣ Method of use [Precautions prior to use] 1) It should never be used, other than those who trained physicians and licensed people, and into the oral cavity to use disposable products, it should not be re-used. 2) Check the packaging. 3) Operation shall be carried out in a clean place, to be so the patient is not contaminated other contaminants during surgery. 4) It shall establish procedures for the accurate examination and treatment planning of oral and systemic conditions of the patient. At this time, there is a need for a consensus among dental technicians, the surgeon, restorative dentist. 5) It should pay particular attention to personal injury due to surgery or heat. 6) Check for damage or discoloration of the product before use and do not use it if found.
※ How to sterilization

Since this is a non-sterilized medical device, you should sterilize it through autoclave method before use. Standard for the autoclave : autoclave at 121℃, pressure of 1.5 for 30 minutes.

1) Supply power to the auto-clave. 2) Place the product in the autoclave. 3) Set the autoclave. (Temperature: 121℃, time: 30 minutes) 4) When finished, take out the product.
▣ How to use [Abutment Design Process] 1) Fabricate model from patient's impression using traditional laboratory techniques. 2) The Model work and appropriate Arum Dentistry scan bodies should be used with Dental CAD/CAM scanner technology to produced digital case model work for implant abutment design. 3) Using dental implant abutment design software, such as 3Shape Implant Designer, design the implant abutment within the following parameters: All digitally-designed Pre-Mill Blank abutments are intended to be sent to an ARUM Dentistry-validated milling center for manufacture.

Parameter	Min (mm)	10Ø Max (mm)	14Ø Max (mm)
Total Height	6.0 mm	16.0mm	16.0mm
Post Height for Single-Unit Restoration	4.0mm	13.0mm	13.0mm
Angle	0°	30°	30°
Wall Thickness	0.5mm	3.8mm	6.0mm
Diameter	Based on minimum wall thickness	9.9mm	13.9mm
Gingival Height	0.5mm	4.0mm	4.0mm

[Table 1. Abutment Design parameter]

※ Note: Abutment parameters may vary, depending on the size of the abutments.

[Fabrication Process (ARUM Dentistry-validated milling center)] CAD/CAM dental systems refers to the software used to both design and mill dental prosthetics. CAD (Computer Aided Design) includes digitally scanning and designing prosthetics, while CAM (Computer Aided Manufacturing) is the process of sending final designed restoration files to the output device and manufacturing them via milling or 3D printing. ARUM Dentistry-validated milling center devices and software are specifically engineered to fit into this digital workflow.
► Digital process 1) Scan : Attach the scan body to the model. Make sure that it is correctly mounted on the implant(fixtures) and tighten it completely with a screw. 2) CAD : The Table1. provided values of the Abutment Parameters MIN/MAX shall be complied with and designed. 3) CAM : Use a proven cam process and refer to the following for connector sizes. 4) Machining 4-1) After the abutment design is complete, the machine is processed using a proven milling machine. 4-2) When fixing the abutment to the machine jig, tighten the specified torque value. The D-cut face and the abutment fastening face must be parallel. Also, the jig of abutment a side should be 90 degrees. 4-3) Once machining is complete, loosen counter-clockwise using a torque wrench with the specified torque value. 4-4) Remove the residuals from the connector with the micro motor, which is commonly used in the LAB, and perform the overall polishing. 4-5) Caution: The abutment screw in the package is for final restoration and must be delivered to the prosthetic dentist. [Clinical Procedure] Clinical procedure to be carried out in the dental practice, following delivery of the restoration from the dental laboratory. 1) Connect the abutment onto the implant. It is recommended the original implant manufacturers prosthetic tooling and torque are applied to the screw. For Abutments the abutment should be torqued to recommended torque value using a driver and Manual Torque Wrench Prosthetic. 2) Once the abutment is inserted into the implant, 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.
▣ Warning - Since product damage and surrounding bone tissue damage can occur, the product should be used only by an experienced clinician. - This product should not be reused and should be applied according to the correct use and purpose. - Defective products should not be used. - This product should not handled carefully to prevent production damage and deformation. - If patients suffer from any incident or adverse event with regard to the device, they must report it to the manufacturer, European Authorized Representative and competent authority.
▣ Caution in Use 1) Cautions on the target age, gender, or health status shall be mentioned in consideration of characteristics of the medical device. - If the condition of patient is not suitable for operation, the clinician should not use this product. 2) Cautions against adverse events that are likely to be incurred after the use of medical device, or fatal adverse events that may be incurred by the careless use, and other accidents shall be mentioned. - Do not use this product for patient with metal allergy. 3) General Cautions - The product should not be used if contaminated by mistake of the operator during operation. - Since all products that are used in the intraoral area are single-use products, they should not be reused. - Implant surgery should be reconsidered when patients have contraindication. ※ A single tooth implant surgery can typically take about one hour from start to finish.
▣ Indication It was designed for dental implant surgery, it is placed on the maxillary or mandibular alveolar bone through a surgical operation to replace the dental root.
▣ Contraindications Contraindications include following, but are not limited to: - Uncontrollable hypertension, diabetes. - Leukemia, hemophilia, thrombopenia. - Patients who have been taking the drugs(osteoporosis) for a long time. - Alcohol dependence, depression, schizophrenia. - Radiation therapy on jaw.
▣ Side Effect
The problem (loss of implant stability, loss of prosthesis, etc.) may occur after implantation, deficient quality and quantity of remaining bone, infection, inferior oral hygiene or uncooperativeness of patient, implant mobility, partial deterioration of tissue, and improper position and arrangement of implants can cause instability. Implant operating procedures are dangerous and may cause dehiscence of certain parts, temporary hypersensitivity reaction, voice disorder, delayed healing, edema, hematoma, gingivitis, and bleeding. Insensibility may occur to the lower lip. Jaw parts from the lower jawbone operation and parts near the nose from the upper jawbone operation may suffer from side effects. Most of them may be temporary but permanent paralysis may occur in very rare cases. This may cause gingival-mucous membrane (gum tissue) ulcer and reacted infection of cellular tissues. However, these are reactions generally from local treatment. Complications found in clinical literatures include initial tooth mobility, Infection, failed osseointegration (removal), paralysis, fracture, prosthetic complications, peri-implantitis, bone loss and gingival recession. After the procedure, some problems (loss of implant fixture, damage of prosthesis, etc.) may occur. The quality and quantitative deficiencies of the remaining bones, infection, poor oral hygiene or non- coordination of the patient, movement of the implants, local tissue degeneration, and the location and arrangement of unsuitable implants can cause these problems.
▣ Storage Method Store at room temperature.
▣ Disposal For disposal, country specific laws and regulations must be observed.
▣ 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

※ This product is a non-sterile medical device.
※ In case of serious accidents, users should inform ARUM DENTISTRY and the authority.

▣ Address and Contact

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

MedNet EC-REP IIb GmbH Borkstrasse 10, 48163 Muenster, Germany
Tel: +49-251-32266-61

▣ Label Symbols

Symbol	Description	Symbol	Description
REF	Catalog Number		Consult Instructions for Use
LOT	Batch Code		Do Not reuse
	Date of Manufacture	NON STERILE	Non-Sterile
	Caution	EC REP	European Authorized Representative
	Legal Manufacturer	CE 1370	CE mark

Instructions For Use (Link Abutment)

[AD-IFU-002 (Rev. 8.0) 2022.06]

▣ Device description
1) Brand Name : Link Abutment
2) Device Name : Abutment & Abutment screw

▣ Intended for use
Implant, endosseous, superstructure An abutment of the implant, which is inserted to support a prosthesis like an artificial tooth to be used for restoring the patient's masticatory function.

▣ Raw Material

Device	Material
Abutment	Ti-6Al-4V Eli
Abutment Screw	Ti-6Al-4V Eli

▣ Method of use [Precautions prior to use]
1) It should never be used, other than those who trained physicians and licensed people, and into the oral cavity to use disposable products, it should not be re-used.
2) Check the packaging.
3) Operation shall be carried out in a clean place, to be so the patient is not contaminated other contaminants during surgery.
4) It shall establish procedures for the accurate examination and treatment planning of oral and systemic conditions of the patient. At this time, there is a need for a consensus among dental technicians, the surgeon, restorative dentist.
5) It should pay particular attention to personal injury due to surgery or heat.
6) Check for damage or discoloration of the product before use and do not use it if found.
※ How to sterilization

Since this is a non-sterilized medical device, you should sterilize it through autoclave method before use. Standard for the autoclave : autoclave at 121 , pressure of 1.5 for 30 minutes.

1) Supply power to the auto-clave.
2) Place the product in the autoclave.
3) Set the autoclave. (Temperature: 121℃, time: 30 minutes)
4) When finished, take out the product.

▣ How to use
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 the prosthesis considering occlusion, intensity, and aesthetics.
3) Finish the surgery after installing the prosthesis.
4) Non-sterile conditions, so use the high-pressure steam sterilization treatment (Autoclave1.5atm, 121℃, 30 min), including surgical instruments before mounting in the oral.
5) Abutment Screw is comply with the recommended torque when signing.
6) It is thoroughly cleaned to eliminate any residual impurities after signing.
7) Do not use other surgical procedure other than for the stated purpose.

▣ Warning
- Since product damage and surrounding bone tissue damage can occur, the product should be used only by an experienced clinician.
- This product should not be reused and should be applied according to the correct use and purpose.
- Defective products should not be used.
- This product should not handled carefully to prevent production damage and deformation.
- If patients suffer from any incident or adverse event with regard to the device, they must report it to the manufacturer, European Authorized Representative and competent authority.

▣ Caution in Use
1) Cautions on the target age, gender, or health status shall be mentioned in consideration of characteristics of the medical device.
- If the condition of patient is not suitable for operation, the clinician should not use this product.
2) Cautions against adverse events that are likely to be incurred after the use of medical device, or fatal adverse events that may be incurred by the careless use, and other accidents shall be mentioned.
- Do not use this product for patient with metal allergy.
3) General Cautions
- The product should not be used if contaminated by mistake of the operator during operation.
- Since all products that are used in the intraoral area are single-use products, they should not be reused.
- Implant surgery should be reconsidered when patients have contraindication.
※ A single tooth implant surgery can typically take about one hour from start to finish.

▣ Indication
It was designed for dental implant surgery, it is placed on the maxillary or mandibular alveolar bone through a surgical operation to replace the dental root.

▣ Contraindications
Contraindications include following, but are not limited to:
- Uncontrollable hypertension, diabetes.
- Leukemia, hemophilia, thrombopenia.
- Patients who have been taking the drugs(osteoporosis) for a long time.
- Alcohol dependence, depression, schizophrenia.
- Radiation therapy on jaw.

▣ Side Effect
The problem (loss of implant stability, loss of prosthesis, etc.) may occur after implantation, deficient quality and quantity of remaining bone, infection, inferior oral hygiene or uncooperativeness of patient, implant mobility, partial deterioration of tissue, and improper position and arrangement of implants can cause instability. Implant operating procedures are dangerous and may cause dehiscence of certain parts, temporary hypersensitivity reaction, voice disorder, delayed healing, edema, hematoma, gingivitis, and bleeding. Insensibility may occur to the lower lip. Jaw parts from the lower jawbone operation and parts near the nose from the upper jawbone operation may suffer from side effects. Most of them may be temporary but permanent paralysis may occur in very rare cases. This may cause gingival-mucous membrane (gum tissue) ulcer and reacted infection of cellular tissues. However, these are reactions generally from local treatment. Complications found in clinical literatures include initial tooth mobility, Infection, failed osseointegration (removal), paralysis, fracture, prosthetic complications, peri-implantitis, bone loss and gingival recession. After the procedure, some problems (loss of implant fixture, damage of prosthesis, etc.) may occur. The quality and quantitative deficiencies of the remaining bones, infection, poor oral hygiene or non- coordination of the patient, movement of the implants, local tissue degeneration, and the location and arrangement of unsuitable implants can cause these problems.

▣ Storage Method
Store at room temperature.

▣ Disposal
For disposal, country specific laws and regulations must be observed.

▣ 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

※ This product is a non-sterile medical device.
※ In case of serious accidents, users should inform ARUM DENTISTRY and the authority.

▣ Address and Contact

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

CE 1370 EC REP **MedNet EC-REP IIb GmbH** Borkstrasse 10, 48163 Muenster, Germany
Tel: +49-251-32266-61

▣ Label Symbols

Symbol	Description	Symbol	Description
REF	Catalog Number		Consult Instructions for Use
LOT	Batch Code		Do Not reuse
	Date of Manufacture		Non-Sterile
	Caution	EC REP	European Authorized Representative
	Legal Manufacturer	CE 1370	CE mark