1. Intended for use

<General>
For the recovery of the patients' masticatory movement, this is an upper structure of the implant to support the prosthetics such as implants. (This is the upper part of the dental implant for the masticatory movement recovery of the deficit teeth)

<Cemented Abutment>
Cemented Abutment is a two-pieces abutment that is first secured to the dental implant with an abutment screw. A crown (the dental prosthesis) is then connected to the abutment with dental cement. This is be used for making a final artificial tooth to provide masticatory and aesthetic functions. Cemented Abutment is supplied non-sterile.

<Angled Abutment>
Angled Abutment is a two-pieces abutment that is first secured to the dental implant with an abutment screw. A crown(the dental prosthesis) is then connected to the abutment with dental cement. This is be used for making a final artificial tooth to provide masticatory and aesthetic functions. Angled Abutment is supplied non-sterile.

<Temporary Abutment>
Temporary Abutment is a two-pieces abutment that is first secured to the dental implant with an abutment screw. A crown(the dental prosthesis) is then connected to the abutment with abutment screw. This is be used for making a temporary artificial tooth to provide masticatory and aesthetic functions while the final prosthesis is made. Temporary Abutment is supplied non-sterile

<Solid Abutment>
Solid Abutment is a one-piece abutment that is first secured to the dental implant without the other component. A crown (the dental prosthesis) is then connected to the abutment with dental cement. This is be used for making a final artificial tooth to provide masticatory and aesthetic functions. Solid Abutment is supplied non-sterile.

<Ball Abutment>
Protect cap is used to protect ingressing other substances after solid abutment that is fixed on the implant. Only temporary cement should be used to secure the protective caps. Protective caps are removed the same way as a temporarily cemented crown. In order to prevent any displacement of the abutment, the protective cap must not be removed using a rotary movement. Protect Cap is supplied non-sterile.

<Multi-Unit Abutment>
Multi-Unit Abutments are intended to be connectors between endosseous dental implants and multiple implant screw-retained restorations.

2. Instruction for Use & Procedure

<Preparations before use>
①Operators must understand the operating procedures and products completely before clinical use. The operators must explain the limitation of implants to patients and the patients must clearly understand the limitations of the implants functions & esthetics.
②The packaging must be opened immediately before use in front of the patient to check for abnormality of product. The product cannot be used when impurity or foreign substance is found.
③Check abnormality and foreign substance in the product prior to use.
④As selecting and fixing implants properly have great influence on the life of the implants, it is essential to follow indicants, contraindications, cautions, and warnings precisely.
⑤Detailed conditions of the patient must be inspected and plans for diagnosis and treatment need to be sufficiently devised before the operation.
⑥In treatment of graft, oral health of the patient must be inspected in detail prior to operation to check for biological and somatological factors that may impede the outcome of operation.
⑦Plans for diagnosis and treatment should precede operation. Loss of graft may occur when patient evaluation and plans for diagnosis and treatment are not carried out properly.
⑧Sterilize the prosthetic components with the autocalvefor 15mins with 132°C or 10mins with 135°C before use.
⑨After the sterilization throughly dry it for 30mins.
⑩Thetreatment of all equipment to be used, must be sterilized in advance.
⑪ For the details of How to use each abutment is please refer to "Prosthetic Procedures".

<Explanation of products>
①Abutment of DIO Implant, treatment equipment and prosthetic material, do the following Classification:

Classification	Product
Dental Implant Superstructure	Cover Screw, Healing Abutment, Healing Cap, Pre-Milled Bar
	Abutment(Cemented, Angled, Solid, Temporary, Mill, Ball, Multi-unit)
	Retainer, Ball Cap, O-Ring, Protect Cap, Abutment Screw, Cylinder(Gold/Plastic/Temporary/Cemented)
Dental Implant Instruments	Protect Cap(Digital, Solid), Ball Abutment Holder

②For operation procedures and detailed instructions and procedures for each product, please see our manual, catalogue, or website.
(www.dioimplant.com/eng/manual.do)
③For product code, specification, date of manufacture, expiration date, please see the label on our product.
④If you want to receive user's manual by mail, please e-mail us at dio@dio.co.kr.
<Method of use>
①After the soft tissues are cured, use the impression materials to take an impression.
②Compare the impression and X-Ray image. Select the type and size of abutment considering the relationship with adjacent teeth.
③Attach the selected abutment in the mouth.
④Cut the attached abutment to an appropriate length to modify its shape.
⑤Take the final impression from the modified abutment and manufacture final prosthesis. The plastic post will be burnt out on the casting process.
⑥After mounting the final prosthesis on top of graft or abutment in the mouth, screw is connected and occlusion between upper and lower jaws is checked for completion.
<Preparations before using the healing abutment>
①A dentist must fully understand the product and sequence of operation before clinical use.
②Detailed inspection on the patient and plans for diagnosis and treatment must be sufficiently carried out prior to operation.
③Product must be selected to fit characteristics of the patient by properly examining X-Ray image.
④Check the packaging status, expiration and damaging of the product.
⑤Since this product is sterilized before supply, it cannot be used if packaging is damaged or opened.
<How to use the healing abutment>
①When two-time operation is selected, connect the cover screw to the implanted fixture.
②After connecting cover screw, suture the gum to hide and protect the graft.
③When one-time operation is selected, connect healing abutment to the implanted fixture.
④After confirming osseo-integration and healing of soft tissues, the operator shall make the decision to remove cover screw or healing abutment and insert prosthesis.
⑤This product is temporarily used during osseo-integration and healing period of soft tissues.
<Storage Condition>
1~30℃

3. Contraindication
Implant operations need to be considered in the following cases.
①Inappropriate positional relationships of the maxillae (insufficient amount of bone)
②Problematic occlusion or functional relationships
③Unrecovered teeth, Bad oral sanitation
④Acute inflammatory disease and infection
⑤Temporary use of specific drugs (anticoagulant, immunosuppressant) and current medicines(corticosteroids, long-term treatment with antibiotics)
⑥Physical and mental stress
⑦Patients with bad compliance, neurosis, mental illness, problematic patients, pregnant patients, and abuse of alcohol and drug
⑧Bone metabolic disorder(osteomalacia, osteitis deformans, dysostosis, menopausal osteoporosis, adolescent diabetes, diabetes level of 300 or higher)
⑨Implant as a focus of potential bacteria growth (artificial heart valves, bacterial endocarditis)
⑩Morbidity of alveolar bone, radiation treatment on weak bones
⑪Xerostomia, hypertrophy of tongue, collagen disorder (dermatosclerosis, rheumatoid arthritis)
⑫Pathological change in oral mucosa (leukoplakia, lichen planus, stomatitis)
⑬Hematological disorder (red blood cell, white blood cell, and blood coagulation system disorder), cardiac and circulatory disorder (arteriosclerosis, high blood pressure of 300 or higher)
⑭General and nutritional status–age (obesity, bad constitution, 5 year survival)

4. Warning
For safe and effective use of DIO Implant Systems, the following are strongly recommended.
①As wrong operation may cause damaged implants or damaged osseous tissues, implants must be operated by an experienced dentist.
②Implants must not be reused and must be applied to meet original purposes.
③Damaged or incorrectly handled product must be removed.
④Inappropriate selection of implants or unstable implants may reduce life of implants.
⑤The product needs to be handled carefully to prevent damaging and deformation.
⑥Misuse of the products may result in demages of the fixture or bone.
⑦Products with flaws must be returned.

5. Precaution
It is essential to conduct on patients who desire to have implant operations and on products thorough preliminary examinations.
①Operation skills required to insert dental implants require professional and complex procedures.
②It is recommended to be trained to insert implants first.
③As for safety of bones for implants, not only visual examination but visible examination such as panorama and root apex radiograph may be used to check determination of anatomical boundaries, occlusion, periodontal status, and alveolar bones.
④Lateral cephalometric radiograph, CT pictures, and MRI pictures will be useful.
⑤Visual inspection of the location for insertion and appropriate radiographs will be necessary for prescription, planning, and use.
⑥Remind patients not to add excessive chewing power during treatment.

6. Surgical Complications and Adverse Effects
After having dental implants inserted, avoid excessive activities. Potential complications which may occur after having dental implants inserted are as follows:
①Implant operating procedures are dangerous and may cause dehiscence of certain parts, temporary hypersensitivity reaction, voice disorder, delayed healing, edema, hematoma, gingivitis, and bleeding.
②Insensibility 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.
③This may cause gingival-mucous membrane (gum tissue) ulcer and reacted infection of cellular tissues. However, these are reactions generally from local treatment.

7. Handling
①Cover screw and healing abutment are products sterilized by radiation.
②Before you use non-sterilized products, make sure that Wrapped Instruments to be sterilized at 132℃ for 15 minutes and then dried 30 minutes before they can be used.
③As plastic products may transform during high pressure steam

sterilization, more than 160℃ of temperature and 0.45 MPa of pressure should not be added.
④The Abutment is to be fabricated with at least a minimum post height of 4 mm above the transmucosal collar.
⑤Type of method used for steam sterilization is "Gravity Displacement"
⑥Non-sterile device components are to be packaged in a "plastic container" that is a FDA-cleared sterilization accessory prior to undergoing steam sterilization.
⑦After use of investment, it should be cooled down gradually to avoid transformation of a fine contraction and expansion when the investment is coagulated.
⑧They should be treated only with exclusive operating instruments.
⑨Tightening torque recommended to 20Ncm. It is recommended to clamp with recommended torque.
⑩The Temporary abutment is use long term temporary restorations that require superior esthetics(Maximum duration : 180 days).

8. Caution

①In order to install the superstructure in the mouth of the patient, the operator must check the degree of osseointegration of implanted fixture with X-ray pictures and percussion before operation.
②An open product or a damaged product must not be used.
③A product contaminated by the operator's mistake during operation must not be used.
④Implant surgery must be considered under side effects and restrictions.
⑤When processing the abutment, its angle should not be processed more than 20°. When this angle range is exceeded, serious side effects can occur. Please be careful as our company is not responsible for such side effects.
⑥The UF(II) Narrow Implant system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of UF(II) Narrow Implant system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
⑦As all products used in the mouth are disposable, they are not be reused.

STERILE R
Sterilized using irradiation

Caution

Date of manufacture

EC REP
Authorized representative in Europe

REF
Catalogue number

Do not reuse
(Reuse prohibited)

Use by (Expiration Date)

CE
0068
CE Marking

LOT
Batch code

Manufacture's Name and Address

Temperature limitation
(Storage Temperature)

EC REP CPMPHARMA – Comércio de Produtos Médicos e Trading, Lda.
Address: Rua 25 de Abril, n.º 265 – Apartado 161, S. Cosme – 4420-356 Gondomar, Portugal
Telephone: +351 224671569
Fax: +351 224647330

DIOPars Corporation
Address: No. 113, Noavari 11 St., Pardis Technology Park, Tehran, Iran.
Tel. +98-21-42893, Postal Code. 1587618415

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