ENGLISH

1. Intended Purpose

① The abutments are placed into a dental implant to provide support for a prosthetic reconstruction. Used by licensed dentist, abutment is intended for use with an endosseous implant to support a prosthetic device in a partially of completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. It is not recommended for patients with incomplete jaw growth. This is in contact with skin and is used for a long term.

② Healing abutment and cover screws are intended for use with the implant system to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Temporary abutment is intended for use with dental implant for temporary restoration of single crowns and ridges in the anterior and posterior region for use up to six months.

③ Diopars Abutments are compatible with Dio Implant system.

2. Indication

The abutment connected to the endosseous dental implant is used to maintain prosthetic restorations such as crowns, bridges, or overdentures to restore the patient's masticatory function.

3. Instruction for Use & Procedure

<Preparations before use>

① Operators 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.

② The packaging must be opened immediately before use in front of the patient to check for abnormality of the product. The product cannot be used when impurity or foreign substance is found.

③ Check abnormality and foreign substance in the product prior to use.

④ As 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.

⑤ Detailed conditions of the patient must be inspected and plans for diagnosis and treatment need to be sufficiently devised before the operation.

⑥ In treatment of graft, the 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 the operation.

⑦ Plans for diagnosis and treatment should precede operation. Loss of graft may occur when patient evaluation and plans for diagnosis and treatment is not carried out properly.

⑧ Upper structure transplanted by high-pressure steam sterilization method (pursuant to ISO 17665-1, 2) is used after sterilizing for 15 minutes at 132℃ using a high-pressure steam sterilizer.

⑨ After sterilizing with a high-pressure steam sterilizer, the implants should be dried for 30 minutes.

⑩ The treatment of all equipment to be used must be sterilized in advance.

<Explanation of products>

① Abutment of Diopars, treatment equipment, and prosthetic material, do the following.

Classification	Product
Dental Implant Superstructure	Cover Screw, Healing Abutment, Closing Screw, Headless Screw, Hybrid Link, Healing Cap, Pre-Milled Bar
	Abutment (Temporary, Cemented, Mill, Angled, UCLA Gold/CCM/Plastic, Solid, Octa, Ball, Custom, Customized, Cast, Digital, Multi unit)
	Retainer, Ball Cap, O-Ring, Protect Cap, Abutment Screw, Cylinder(Gold/Plastic/Temporary/Cemented),
Dental Implant Instruments	Impression Coping(Pick up/Transfer), Plastic Coping, Impression Cap, Fixture Mount
Dental Implant Pore Materials	Analog(Fixture, Solid ,Ball, Octa)
Medical Guide	Scan Adapter, H-Scan Body,

② For operation procedures and detailed instructions and procedures for each product, please see our manual, catalog, or website. (www.diopars.com/IFU)

③ For product code, specification, date of manufacture, expiration date, please see the label on our product.

④ If you want to receive user's manual by mail, please e-mail us at info@diopars.com

<Method of use>

① After the soft tissues are cured, use the impression materials to take an impression.

② Compare the impression and X-Ray image. Select the type and size of abutment considering the relationship with adjacent teeth.

③ Attach the selected abutment in the mouth.

④ Cut the attached abutment to an appropriate length to modify its shape.

⑤ Take the final impression from the modified abutment and manufacture the final prosthesis. During the manufacture of the prosthesis, the plastic sleeve is burnt and removed.

⑥ After mounting the final prosthesis on top of graft or abutment in the mouth, the screw is connected and occlusion between upper and lower jaws is checked for completion.

<Preparations before using the healing abutment>

① A dentist must fully understand the product and sequence of operation before clinical use.

② Detailed inspection on the patient and plans for diagnosis and treatment must be sufficiently carried out prior to operation.

③ Product must be selected to fit the characteristics of the patient by properly examining the X-Ray image.

④ Check the packaging status, expiration and damaging of the product.

⑤ Since this product is sterilized before supply, it cannot be used if the packaging is damaged or opened.

<How to use the healing abutment>

① When the two-time operation is selected, connect the cover screw to the implanted fixture.

② After connecting cover screw, suture the gum to hide and protect the graft.

③ When the one-time operation is selected, connect healing abutment to the implanted fixture.

④ After confirming osseointegration and healing of soft tissues, the operator shall make the decision to remove a cover screw or healing abutment and insert prosthesis.

⑤ This product is temporarily used during osseointegration and healing period of soft tissues.

4. **Contraindication**

Contraindications customarily associated with elective oral surgery should be observed when selecting patients. These include, but are not limited to:

① Implant operations need to be considered in the following cases.

② Inappropriate positional relationships of the maxillae (insufficient amount of bone)

③ Problematic occlusion or functional relationships

④ Unrecovered teeth, Bad oral sanitation

⑤ Acute inflammatory disease and infection

⑥ Temporary use of specific drugs (anticoagulant, immunosuppressant) and current medicines (corticosteroids, long-term treatment with antibiotics)

⑦ Physical and mental stress

⑧ Patients with bad compliance, neurosis, mental illness, problematic patients, pregnant patients, and abuse of alcohol and drug

⑨ Bone metabolic disorder (osteomalacia, osteitis deformans, dysostosis, menopausal osteoporosis, adolescent diabetes, diabetes level of 300 or higher)

⑩ Implant as a focus of potential bacteria growth (artificial heart valves, bacterial endocarditis)

⑪ Morbidity of alveolar bone, radiation treatment on weak bones

⑫ Xerostomia, hypertrophy of tongue, collagen disorder (dermatosclerosis, rheumatoid arthritis)

⑬ Pathological change in oral mucosa (leukoplakia, lichen planus, stomatitis)

⑭ Hematological disorder (red blood cell, white blood cell, and blood coagulation system disorder), cardiac and circulatory disorder. (Arteriosclerosis, high blood pressure of 300 or higher)

⑮ General and nutritional status – age (obesity, bad constitution, 5-year survival)

5. **Warning**

Abutment must only be used by licensed dentists with training and experience in oral surgery, prosthetics as well as diagnosis and pre-operative planning.

For safe and effective use of DIO Implant Systems, the following are strongly recommended.

① Must be performed and handled by a licensed dentist who is also obliged to study the latest developments in regard to this Diopars product and its applications regularly. Otherwise, it may cause damages to the osseous tissues and to the implant such as fracture.

② Implants must not be reused and must be applied to meet original purposes.

③ Damaged or incorrectly handled product must be removed.

④ Inappropriate selection of implants or unstable implants may reduce the life of implants.

⑤ The product needs to be handled carefully to prevent damaging and deformation.

⑥ This product may result in galvanic corrosion when used with a fixture made of titanium material.

⑦ Products with flaws must be returned.

⑧ Do not use other products made by third parties in conjunction with DIO products.

⑨ The Abutment 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 Abutment in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

6. **Precaution**

It is essential to conduct on patients who desire to have implant operations and on products thorough preliminary examinations.

① Operation skills required to insert dental implants require professional and complex procedures.

② It is recommended to be trained to insert implants first.

③ As for the 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.

④ Lateral cephalometric radiograph, CT pictures, and MRI pictures will be useful.

⑤ Visual inspection of the location for insertion and appropriate radiographs will be necessary for a prescription, planning, and use.

⑥ Remind patients not to add excessive chewing power during treatment.

7. **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:

① Implant operating procedures are dangerous and may cause dehiscence of certain parts, temporary hypersensitivity reaction, voice disorder, delayed healing, edema, hematoma, gingivitis, and bleeding.

② 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.

③ This may cause gingival-mucous membrane (gum tissue) ulcer and reacted infection of cellular tissues. However, these are reactions generally from local treatment.

8. **Handling**

① Cover screw and healing abutment are products sterilized by radiation.

② Before you use non-sterilized products, make sure to sterilize them at 132℃ for 15 minutes with a high-pressure steam sterilizer.

③ After sterilizing with a high-pressure steam sterilizer, the implants should be dried for 30 minutes.

④ As plastic products may transform during high-pressure steam sterilization, more than 160℃ of temperature and 0.45MPa of pressure should not be added.

⑤ UCLA Gold /CCM Abutment and Mill Abutment are to be fabricated with at least a minimum post height of 4 mm above the transmucosal collar.

⑥ Type of method used for steam sterilization is “Gravity Displacement”

⑦ Non-sterile device components are to be packaged in a “plastic container” that is an FDA-cleared sterilization accessory prior to undergoing steam sterilization.

⑧ UCLA Gold /CCM Abutment and Mill Abutment are to be straight abutments only during the customization.

⑨ After use of investment, it should be cooled down gradually to avoid transformation of a fine contraction and expansion when the investment is coagulated.

⑩ They should be treated only with exclusive operating instruments. It is recommended to clamp with recommended torque.

9. **Caution**

① In 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 an operation.

② An open product or a damaged product must not be used.

③ A product contaminated by the operator’s mistake during operation must not be used.

④ Implant surgery must be considered under side effects and restrictions.

⑤ When processing the abutment, its angle should not be processed more than 29.8°. When this angle range is exceeded, serious side effects can occur. Please be careful as our company is not responsible for such side effects.

⑥ As all products used in the mouth are disposable, they are not be reused.

10. **Side Effects**

Fever, Edema, Inflammation, Infection, Tissue necrosis, Oral mucosal damage, Bone tissue damage, Tissue damage

11. **Gamma Sterilized medical devices**

Healing Abutment and cover screw are delivered sterile. The intact sterile packaging protects the sterilized implant from outside influences and, if stored correctly, ensures sterility up to the expiration date. When removing the implant from the sterile packaging, rules of asepsis must be observed. The sterile packaging must not be opened until immediately prior to insertion of the implant. Implants with damaged sterile packaging must not be used. It is recommended to have a replacement implant at hand.

12. **Disposal**

Disposal should be handled environmentally sustainable according to local regulations. Hazardous waste for contaminated devices or sharps should be disposed of in appropriate containers which meet the specific technical requirements.

13. **Implant card**

The implant card includes contents such as ‘Identification of the device’, ‘Device name’, ‘Lot number’ and ‘Manufacturer’s name, address and website’.

14. **Storage Condition**

Temperature: 1~30°C , Humidity : 0~80%

※ Significant accidents involving the device should be reported to the manufacturer and user and / or the relevant authorities of the Member State where the patient is located.

※ Summary of Safety and Clinical Performance (SSCP) shall be kept updated in Eudamed (https://ec.europa.eu/tools/eudamed).

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 KR: 배치(batch)코드 US, GB: Batch code RU: Номер партии DE: Batch-Code ES: Número de lote BR, PT: Código de lote IT: Numero di lotto FR: Número de lot	 KR: 모델명, 카탈로그번호 US, GB: Catalogue number RU: Каталог номер DE: Katalog Nummer ES: Catalog numerus BR, PT: Número de catálogo IT: Numero di catalogo FR: Numéro de catalogue	 KR: 비멸균 US, GB: Non-sterile RU: Нестерильно DE: Nicht steril ES: Np estéril BR, PT: Não-esterilizado IT: Non sterile FR: Non Stérile	 KR: 주의 US, GB: Caution RU: Внимание! DE: Achtung ES: Precaución BR, PT: Atenção IT: Attenzione FR: Attention
 KR: 사용설명서 참조 US, GB: Consult instructions for use RU: См. инструкцию по применению DE: Gebrauchsanweisung beachten ES: Consultar las instrucciones de uso BR, PT: Consultar as instruções de utilização IT: Consultare le istruzioni per l'uso FR: Consulter les instructions d'utilisation	 KR: 유효기간 US, GB: Use by (Expiration Date) RU: Срок годности DE: Verfallsdatum ES: Plazo de Validez BR, PT: Uso por (Data de validade) IT: Utilizzare entro (Data di scadenza) FR: Utiliser jusqu'à (Date de péremption)	 KR: 의료기기 US, GB: Medical Device RU: Медицинское оборудование DE: Medizinprodukt ES: Producto sanitario BR, PT: Dispositivo medico IT: Dispositivo medico FR: Dispositif medical	 KR: 재사용 금지 US, GB: Do not reuse (Reuse prohibited) RU: Для одноразового использования DE: Wiederverwendung verboten ES: Prohibido del uso de la regeneracion BR, PT: Não reutilizar (reutilização permitida) IT: Non riutilizzare (il riutilizzo è proibito) FR: Ne pas réutiliser (Réutilisation interdite)
 KR: 제조업자 US, GB: Manufacture RU: Производитель DE: Hersteller ES: Fabricante BR, PT: Fabricante IT: Produttore FR: Fabricant	 KR: 제조일자 US, GB: Date of manufacture RU: Дата изготовления DE: Datum der Herstellung ES: Fecha de la Fabrica BR, PT: Data de fabricação IT: Data di produzione FR: Date de fabrication	 KR: 포장이 손상 되었을 경우 사용하지 마십시오. US, GB: Do not use if package is damaged RU: не использовать, если упаковка повреждена Род-Айленд Делавэр DE: Nicht verwenden, wenn das Paket beschädigt ist ES: No lo use si el paquete está dañado BR, PT: Não use se a embalagem estiver danificada IT: Non utilizzare se la confezione è danneggiata FR: Ne pas utiliser si l'emballage est endommagé	 KR: 방사선 멸균 US, GB: Sterilized using irradiation RU: Стерилизованы с Помощью облучения гамма учами DE: Strahlensterilisation ES: Esterilizacion de Radiacion BR, PT: Esterilizado por irradiação IT: Sterilizzato mediante irradiazione FR: Dispositif stérilisé par rayon Gamma
 KR: 보관온도 US, GB: Temperature limitation (Storage Temperature) RU: Температурное ограничение DE: Lagertemperatur ES: Temperatura de conservacion BR, PT:Limite de temperatura(temperatura de armazenamento) IT: Limiti di temperatura (Temperatura di stoccaggio) FR: Limite de Temperature (Température de conservation)			