1. **Indication for use**

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)

2. **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 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 indications, 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, 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.
   7. Plans 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.
   8. Sterilize the prosthetic components with the autoclave for 15mins with 132°C or 10mins with 135°C before use.
   9. After the sterilization throughly dry it for 30mins.
   10. The treatment of all equipment to be used, must be sterilized in advance.

   **Explanation of products**
   1. Abutment of DIO Implant, treatment equipment and prosthetic material, do the following.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Product</th>
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<tbody>
<tr>
<td>Dental Implant</td>
<td>Abutment (Temporary, Cemented, Mill, Angled, UCLA Gold/CCM/Plastic, Solid, Octa, Ball, Custom, Customized, Cast)</td>
</tr>
<tr>
<td>Superstructure</td>
<td>Retainer, Ball Cap, O-Ring, Protect Cap, Abutment Screw, Cylinder(Gold/Plastic/Temporary/Cemented),</td>
</tr>
<tr>
<td></td>
<td>Impression Coping(Pick up/Transfer), Plastic Coping, Impression Cap, Fixture Mount</td>
</tr>
<tr>
<td>Instruments</td>
<td>Analog(Fixture, Solid ,Ball, Octa)</td>
</tr>
<tr>
<td>Pore Materials</td>
<td>Scan Adapter, Hi-Scan Body.</td>
</tr>
<tr>
<td>Medical Guide</td>
<td></td>
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</tbody>
</table>

   2. For operation procedures and detailed instructions and procedures for each product, please see our manual, catalogue, or website.
   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 dio@dio.co.kr.

   **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 final prosthesis. The plastic post will be burnt out on the casting process.
   6. After 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**
   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 characteristics of the patient by properly examining 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 packaging is damaged or opened.

   **How to use the healing abutment**
   1. When 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 one-time operation is selected, connect healing abutment to the implanted fixture.
   4. After confirming osseo-integration and healing of soft tissues, the operator shall make the decision to remove cover screw or healing abutment and insert prostheses.
   5. This product is temporarily used during osseo-integration and healing period of soft tissues.

   **Storage Condition**
   Room Temperature

3. **Contraindisation**

Implant operations need to be considered in the following cases.

1. Inappropriate positional relationships of the maxillae (insufficient amount of bone)
① Problematic occlusion or functional relationships
② Unrecovered teeth, Bad oral sanitation
③ Acute inflammatory disease and infection
④ Temporary use of specific drugs (anticogulant, immunosuppressant) and current medicines (corticosteroids, long-term treatment with antibiotics)
⑤ Physical and mental stress
⑥ Patients with bad compliance, neurosis, mental illness, problematic patients, pregnant patients, and abuse of alcohol and drugs
⑦ Bone metabolic disorder (osteomalacia, osteitis deformans, dysostosis, menopausal osteoporosis, adolescent diabetes, diabetes level of 300 or higher)
⑧ Implant as a focus of potential bacteria growth (artificial heart valves, bacterial endocarditis)
⑨ Morbidity of alveolar bone, radiation treatment on weak bones
⑩ Xerostomia, hypertrophy of tongue, collagen disorder (dermatosclerosis, rheumatoid arthritis)
⑪ Pathological change in oral mucosa (leukoplakia, lichen planus, stomatitis)
⑫ 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)
⑬ General 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.
① As wrong operation may cause damaged implants or damaged osseous tissues, implants must be operated by an experienced dentist.
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 life of implants.
⑤ The product needs to be handled carefully to prevent damaging and deformation.
⑥ Misuse of the products may result in demages of the fixture or bone.
⑦ Products 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.
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 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 prescription, planning, and use.
⑥ Remind 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:
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.

7. 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 120~135°C for 5~30 minutes with a high pressure steam sterilizer.
③ After sterilizing with a high pressure steam sterilizer, the prosthetic components should be dried for 30 minutes.
④ As plastic products may transform during high pressure steam sterilization, more than 160°C of temperature and 0.45MPa of pressure should not be added.
⑤ UCLA Gold / ICOM 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 a FDA-cleared sterilization accessory prior to undergoing steam sterilization.
⑧ UCLA and Gold Abutment, and Mill Abutment are straight type abutments for customized prosthetics.
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.

8. 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 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.
### DIO Corporation (Information of Symbol)

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<th>Symbol</th>
<th>Description</th>
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