# INSTRUCTIONS FOR USE DENTAL IMPLANT SYSTEM
## Endosteal Implant / Prosthetic Parts

### Manufacturing Company

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### User Contract

The user agrees that he/she is informed about the conditions in this instruction book which is valid as a contract and that he/she approves the conditions.

### General Properties

The Dental Implant System consists of surgical, prosthetic and dental lab components. There are no specified indications of application for various implant forms and regulations.

The implants and prosthetic parts in these Instructions:

Endosteal implant (fixture): It is an artificial tooth root that is placed in the upper or bottom jawbone and that is used to support a crown, bridge or denture replacing one or more missing teeth. It is a pure titanium (grade 4) screw, it is screwed into the jawbone. Its surface is smoothed with the SLA process. It is made in various diameters and lengths to meet different anatomical needs. It is offered as sterile.

Implant cap: It is a cap / cap screw that is used so that no tissue gets in once the implant is placed inside the bone. It is offered as sterile in packaging along with the implant. It is made out of Ti6Al4V eli. It is sized based on the implant diameter.

Prosthetic Parts:

Healing Abutment/ Healing cup: It is a component that is used so that the gum and the soft tissue on the implant are shaped to fit the upper structure after the osseointegration stage (about 3-4 months after the implantation), it is made out of Ti6Al4V eli. It is presented as nonsterile. It is made in different designs and sizes so that it could be used in different regions and anatomies; There are the Standard, Slim and Shift models. The implant cap is removed and the healing cup is placed. And the healing cup is replaced by Abutment.

Temporary Abutment: It is an abutment that is under the temporary tooth (crown) in a temporary tooth application that is performed so that the patient is aesthetic and not missing teeth in his/her daily life, especially in the frontal (anterior) region implant applications; that connects the temporary tooth with the implant and that is made out of Ti6Al4V eli or PEEK. It is made in various sizes and designs so that different anatomical needs can be met.

Abutment: It is the interconnecting component that is under the artificial tooth (crown) and that joins the artificial tooth with the endosteal implant and keeps them together. The abutment is fixed with an abutment screw onto the endosteal implant. It is made out of Ti6Al4V eli, it is provided as nonsterile. It is made in different models and sizes so that it can be used in the different regions on the jaw. It is modelled plain, at 15°, 25° angles; Aesthetic, at 15°-25° angles.

Ball Socket: It is the component that allows the ball abutment which is fitted onto the implant that has been applied on the patient's bone in the total jaw denture applications to be bonded on the denture palate. This way, the patient can take the denture on and off when he/she wishes. It is made out of Ti6Al4V eli. It is provided as nonsterile.

Abutment Screw: It goes through the abutment and goes into the endosteal implant and makes sure that the abutment and the implant are fixed together. It is made out of Ti6Al4V eli, it is offered as nonsterile.

### Material-Composition

The implants constituting the system are made out of raw materials as per the specifications as follows;

Ti6Al4V ELI alloy (grade 5) : ASTM F136 and ISO 5832-3
Pure Titanium (grade 4): ASTM F67 and ISO 5832-2
PEEK Optima by Invibio : ASTM F2026

### Indications

The dental implant system is for the rehabilitation of patients who have lost all or some of their teeth. Endosteal implant is designed for use to ensure integration with the bone (osseointegration). Implants support the bridges and dentures that can be surgically removed with single restorations or that are fixed and removable.

Single piece Endosteal implant (Implant P) is also an indication for immediate loading as well as the suitable occlusal loading once a good primary stability is achieved.

### Contraindications

The contraindications include but are not limited to the following:
• Limited bone density and soft tissue, insufficient bone quality;
• Localized bone deformities;
• Localized infection;
• Hematological disorders (leukemia, hemophilia, etc.)
• Oral infections or tumors
• Like uncontrollable parafunctional habits; teeth grinding, clenching. *Untreatable occlusal defects or articulation disorders. *Congenital or acquired mental disorders or neuroses that prevent the treatment
• Connective tissue, endocrine system, cardiovascular and other system disorders that will influence the treatment negatively or prevent healing

• Pregnancy, osteoporosis, alcohol - drug use, cancer patients undergoing chemotherapy and radiotherapy, the age of the patient, anemia, patients with metal allergies, diabetes mellitus, regular steroid and anticoagulant use, any disease that would affect the regeneration process of the bone negatively, rheumatic diseases, any physical and/or mental disorders that would affect the patient's recovery and implant use negatively should be carefully evaluated by the doctor. Its use is contraindicated in all such cases.

### Potentially Adverse Effects

Potentially adverse incidents can be listed (but are not limited to) as follows:

Short-term postop (temporary):
-Edema, pain, difficulty with speech-swallowing, bleeding, infection
-Temporary nerve damage, localized sensitivity,

Postoperative complications that can be permanent long-term:
-Nonunion of bone, bone loss
-The implant and/or abutment breaking, getting loose
-Chronic pain
-Damage in adjacent teeth
-Localized-systemic infection, peri-implantitis

A revision surgery might be needed for the abovementioned adverse effects.

### Warnings

The safety and efficiency of using this device aside from the circumstances listed in the indications section are unknown.

The surgeon shall be responsible for any incidents to occur out of nonconformance with the principles explained herein.

### Warnings - Preoperative

1. The implantation of implant systems and prosthetic treatment should only be performed by experienced dentists and oral surgeons who have received special training on the use of such systems. Because this is a technically challenging procedure which poses a risk of getting serious injury for the patient.

2. A successful outcome cannot be obtained in every surgical case. The use of his product will fail with a patient with insufficient bone capacity and in situations of nonunion. In this case, the twisting, dismantling and/or breaking of the device(s) will take place eventually.

3. The pre- and postoperative procedures including the surgical techniques, selecting and placing of the implants appropriately are important matters that need to be taken into consideration in the use of the system by the surgeon. In addition, selecting the right patient and his/her adaptation during the postoperative period will significantly affect the results.

4. The feasibility of the bone's height and width should be determined during the planning stage. The feasibility of the bone structure and the optimal implant location should be determined with the suitable radiographic method to avoid structures like the mandibular canal, maxillary sinus, soft tissue gaps and adjacent teeth.

5. Small sized implants and angled abutments are not recommended for the posterior region of the mouth. Angled

abutments with narrow platforms should only be used for low mechanical loading cases. Not recommended for placing in the molar area.

6. Using excessive force during implantation might damage the integrity of the implant and the patient. The necessary care should be taken for the implant and the patient throughout the operation. A maximum torque of 35 Nm should be used while placing the implant; and a maximum torque of 25 Nm for the abutments.

7. DO NOT REUSE THE IMPLANTS. The implants are disposable. Dispose of the implants that have been used, are damaged or otherwise suspicious.

8. The expiration dates of use and the label information of the implants that are offered as sterile as well as whether the packaging is whole and damage-free should be checked. Do not use devices with damaged and deformed packaging and those that have expired.

9. Do not resterilize the implants that have damaged packaging and that have lost their sterility. Do Not Use on the Patient.

10. The endosteal implant and the prosthetic parts are compatible with each other. Cannot be used with the products of another company.

11. The indications, contraindications, warnings and precautions provided in this document should be communicated to the patient.

## Warnings - Postoperative

• The patient should be informed by the surgeon about the postoperative eating-drinking restrictions and oral hygiene. The patient should follow the instructions and warnings of the doctor and avoid behaviors that will delay bone recovery and that might affect the treatment negatively such as consumption of excessive alcohol, drugs or smoking.

• The patient should be monitored during the postoperative period in order to confirm whether the fusion has taken place. As the delay of the fusion will cause the implants to get deformed, loose, move or break, the situation should be diagnosed early and the implants should be revised before significant damage occurs.

• The patient should be monitored at least once a year with routine examination. The titanium implant might suffer corrosion due to the decrease of the gum line with time because of gum issues, oral hygiene, oral pH, eating and drinking habits, and use of toothpaste containing fluoride. The patient should be informed about postoperative use and care including using fluoride-free toothpaste and should be monitored on a regular basis.

## FOR DEVICES THAT ARE PROVIDED AS NONSTERILE: Sterilization

Nonsterile implants are offered packaged inside locked bottles inside a clean room. Please first check that the Packaging is damage-free and in good condition. Do not use products with damaged packages.

Sterilization:

The implants that are placed in a sterile area are taken out of the bottle and placed onto a sterilization tray.

It is recommended that the fully loaded implants are sterilized by the hospital with steam by using the repositioning autoclave cycle at a temperature of 134 ° C (274 ° F) for at least 5 minutes of exposure with a drying period of 15 minutes.

When a filter paper sterilization container is used, check the durability of the containers before use.

The use of the other sterilization methods shall be the under the responsibility of the user. INOVAMED does not take any responsibility. Additional information can be provided upon request.

## MRI Compatibility

No studies have been conducted regarding the MRI compatibility of the implants.

## Storage Conditions

Sterile implants:

Should be stored in its original packaging in a dry place away from direct sunlight, between 15-25 °C. The necessary precautions should be taken so that the packaging does not get damaged.

Nonsterile implants: Should be stored in closed container/-box away from dust and dirty in dry place, protected from direct sunlight. It should be sterilized and quickly dried before use.

## Expiration Date

For Sterile Devices: 3 year from the manufacturing date.

For nonsterile implants made of titanium alloy: 10 years from the manufacturing date.

Do not use after the expiration date.

## Safe Disposal

Each implant should be disposed of after use and should never be reused. Implants that have come in contact with the patient, have been used, or have been surgically removed from the patient should be considered as medical waste and contaminated product.

Make sure that the implant that is disposed of does not pose any threats for children, stray animals and the environment when you dispose of it. The disposal procedure is governed by the hospitals as per the local regulations.

## Feedback

All professionals (customers or users) encountering any anomalies in the services and/or matters of quality, specification, resistance, reliability, safety, efficiency and/or performance in the INOVAMED products should notify INOVAMED or an authorized representative. This representative should notify INOVAMED of such claim as soon as possible using an Event document.

A failure or damage in the system or any anomaly in the user instructions will cause deterioration in a patient's or user's state of health, please immediately notify via phone or fax. INOVAMED cannot be held responsible for accidents occurring due to the nonconformance with the principles stated on this Instruction page.

## Semboller

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|  | **Do Not Reuse** |
|  | **Storage temperature limit** |
|  | **Manufacturer** |
|  | **Do not use damaged products** |
|  | **Read the Instructions for Use** |
|  | **Nonsterile (For the nonsterile prosthetic parts)** |
|  | **Expiration Date** |
|  | **Attention (Read the Warnings and Precautions)** |
| LOT | **Lot no** |
| REF | **Reference no** |
|  | **Protect from Direct Sunlight** |
| CE 2292 | **Notified Body** |
|  | **Manufacturing Date** |
|  | **Do not resterilize** |
| STERIE R | **Gamma Sterilization** |
|  | **Keep in a dry place** |

***You can refer to the CK06 Surgical Instructions for the details of the surgical procedure.***