INSTRUCTIONS FOR USE
DENTAL IMPLANT SYSTEM
Endosteal Implant and Prosthetic Parts

Manufacturer

İNOVAMED BİYOTEKNOLOJİLERİ MEHMET HAFIZOĞLU VE ÖMER FARUK HAFIZOĞLU KOLLEKTİF ŞİRKETİ

İstanbul Trakya Serbest Bölgesi Ferhatpaşa Sb Mah. Gonca Sokak 1.Kısım Beton Depo Apt. No:4/Z13 Çatalca İstanbul Türkiye

T: +90 216 549 50 94 info@inovamed.com.tr www.inovamed.com.tr

User Agreement

The user acknowledges that they are aware of the terms and conditions in this tariff schedule, which is valid as a contract, and that they accept the terms and conditions.

Device Description

The Dental Implant System consists of surgical, prosthetic, and dental laboratory components. There are no specific application indications defined for various implant shapes and configurations.

The implant and prosthetic components included in this Guide:

Endosteal implant (fixture): An artificial tooth root made of titanium that is placed in the upper or lower jawbone and used to support a crown, bridge, or denture that replaces one or more missing teeth. It is a pure titanium (grade 4) screw that is screwed into the jawbone. Its surface is roughened by SLA treatment. It is produced in various diameters and lengths to meet different anatomical needs. It is supplied sterile.

Implant cap: A cap/cap screw used to prevent tissue from entering the implant once it is placed into the bone. It is supplied sterile in the same packaging as the implant. It is made of Ti6Al4V alloy. It is sized according to the implant diameter.

Prosthetic Components:

Healing Abutment/Healing Cup: This component is used after the osseointegration phase (approximately 3-4 months after implantation) to shape the gum tissue and soft tissue over the implant to be suitable for the superstructure. It is made of Ti6Al4V alloy. It is supplied non-sterile. It is manufactured in different designs and sizes for use in different areas and anatomies; Standard, Slim, and Shift models are available. The implant cap is removed and the healing abutment is placed. The healing abutment is then replaced by the Abutment.

Temporary Abutment: Especially in implant applications in the frontal (front/anterior) region, it is a Ti6Al4V or PEEK abutment that remains under the temporary tooth (crown) and connects the temporary tooth to the implant, allowing the patient to have a temporary tooth for aesthetic and daily life purposes. It is produced in various sizes and designs to meet different anatomical needs.

Abutment: An intermediate connecting piece that remains under the artificial tooth (crown) and connects and holds the artificial tooth and the endosteal implant together. The abutment is fixed to the endosteal implant with an abutment screw. It is made of Ti6Al4V alloy and is supplied non-sterile. It is produced in different models and sizes for use in different areas of the jaw. It is modeled as Straight, 15°, 25° angled; Aesthetic and Aesthetic 15°-25° angled, T-Base, MU Abutment, Straight, 15°, 25° angled.

Ball Socket (Locator): In complete denture applications, this is the component that secures the ball abutment, mounted on the implant placed in the patient's bone, to the denture base. This allows the patient to remove and replace the denture as desired. It is made of Ti6Al4V alloy. Supplied non-sterile.

Support Screw (Abutment Screw): Passes through the support and into the endosteal implant, securing the support and implant together from the inside. Made of Ti6Al4V alloy, supplied non-sterile.

Materials

The implants comprising the system are manufactured from raw materials that comply with the following specifications:

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 intended for the rehabilitation of patients who are completely or partially edentulous. The endosteal implant is designed to be used in a manner that allows for integration with the bone (osseointegration). Implants support single restorations, as well as surgically removable or fixed and removable bridges and prostheses.

Single-piece endosteal implant (Implant P) is also indicated for immediate loading with appropriate occlusal loading once good primary stability has been achieved..

Contra-indications

Contraindications include, but are not limited to:
*Limited bone volume and soft tissue coverage, poor bone quality.
*Local bone defects.
*Local infection.
*Hematological disorders (leukemia, hemophilia, etc.)
*Intraoral infections or tumors.
*Uncontrollable parafunctional habits, such as teeth grinding or clenching.
*Untreatable occlusal or articulation disorders.
*Serious congenital or acquired mental disorders or neurological disorders that prevent treatment.
*Connective tissue, endocrine system, cardiovascular and other system disorders that will negatively affect treatment or prevent healing

* Pregnancy, osteoporosis, alcohol – drug use, cancer patients undergoing chemotherapy and radiotherapy, patient age, anemia, patients with metal allergies, diabetes mellitus, regular steroid or anticoagulant use, any disease that may adversely affect the bone regeneration process, rheumatic diseases, any physical and/or mental disorder that may adversely affect the patient's recovery and implant use should be carefully evaluated by the doctor. Use is contraindicated in all these cases.

Potantial Adverse Events

Potential adverse events may include the following (but are not limited to):
Short-term (temporary) post-operative:
-Swelling, pain, difficulty speaking or swallowing, bleeding, infection
-Temporary nerve damage, local sensitivity

Long-term complications that may be permanent after surgery:
-Non-union of bone, bone loss
-Fracture or loosening of the implant and/or abutment
-Chronic pain
-Damage to adjacent teeth
-Local-systemic infection, peri-implantitis
Revision surgery may be required due to the above undesirable effects.

Warnings

The safety and efficacy of this device for use in conditions other than those listed in the indications section are unknown.

The surgeon is responsible for any incident arising from failure to comply with the principles outlined here.

Warnings – Before Surgery

1. The implantation of implant systems and prosthetic treatment should only be performed by experienced dentists and oral surgeons who have received specialized training in the use of these systems. This is because it is a technically challenging procedure that poses a serious risk of injury to the patient.

2. Successful outcomes cannot always be guaranteed in every surgical case. The use of this product will not be successful in patients with insufficient bone capacity or in cases where non-union develops. In such cases, the device(s) will eventually bend, loosen, become dislodged and/or break.

3. Surgical techniques, including the appropriate selection and placement of implants, preoperative and operative procedures, are important considerations for the successful use of the system by the surgeon. In addition, the selection of suitable patients and compliance in the post-operative period will greatly affect the results.

4. During the planning phase, the suitability of bone height and width must be determined. Using appropriate radiographic methods, the suitability of the bone structure and the optimal implant position should be determined to avoid structures such as the mandibular canal, maxillary sinus, soft tissue spaces, and adjacent teeth.

5. Small-diameter implants and angled abutments are not recommended for the posterior region of the mouth. Narrow-platform angled abutments should only be used in cases of low mechanical loading. Their placement in the molar region is not recommended.

6. Excessive force during implantation may damage the integrity of the implant and harm the patient. Care must be taken for both the implant and the patient during surgery. A maximum torque of 35 Nm should be used when placing the implant; a maximum torque of 25 Nm should be used when placing the abutments.

7. DO NOT REUSE IMPLANTS. Implants are single use only. Discard any used, damaged, or otherwise suspect implants.

8. For implants supplied sterile, check the expiry date, label information, and that the packaging is intact and undamaged before use. Do not use devices with damaged or compromised packaging or devices past their expiry date.

9. Do not re-sterilize implants with damaged packaging or compromised sterility. Do not use them on patients.

10. Endosteal implants and prosthetic components are compatible with each other. They cannot be used together with products from other manufacturers.

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

Warnings- After Surgery

*The patient should be informed by the surgeon about dietary restrictions and oral hygiene during the postoperative period. The patient should comply with the doctor's instructions and warnings and avoid behaviors that may delay bone healing and adversely affect treatment, such as excessive alcohol consumption, smoking, and use of narcotic substances.

*The patient should be monitored during the post-operative period to confirm whether fusion has occurred. Delayed fusion can cause implants to deform, loosen, shift position, or break. Therefore, the condition should be diagnosed early and the implants revised before serious damage occurs.

*The patient should be monitored with routine check-ups at least once a year. Over time, the gum level may decrease due to gum problems. Titanium implants may corrode depending on oral hygiene, oral pH, eating and drinking habits, and the use of fluoride toothpaste. The patient should be informed about post-operative use and care, including the use of fluoride-free toothpaste, and should be monitored regularly.

FOR NON-STERILE DEVICES:
Sterilization

Non-sterile implants are supplied packaged in sealed bottles within a clean room. First, check that the packaging is undamaged and in good condition. Do not use products with damaged packaging.

Sterilization:

Implants taken to a sterile area are removed from the vial and placed in a sterilization tray.

It is recommended that fully loaded implants be steam sterilized by the hospital using a displacement autoclave cycle at 134°C (274°F) for a minimum exposure time of 5 minutes with a 15-minute cooling period.

When using paper filter sterilization trays, check the integrity of the trays before use.

The use of other sterilization methods is the responsibility of the user. INOVAMED accepts no liability. Additional information can be provided upon request.

MR Compatibility

No studies have been conducted on the MR compatibility of implants.

Storage

Sterile implants:

They should be stored in their original packaging in a dry environment, protected from direct sunlight, at temperatures between 15-25°C. Necessary precautions should be taken to prevent damage to the packaging.

Non-sterile implants: should be stored in a closed container/box in a dry environment, protected from direct sunlight and away from dust and dirt. They should be sterilized before use and used promptly.

Expiry Date

For sterile devices: 3 years from the date of manufacture.
For non-sterile titanium alloy implants: 10 years from the date of manufacture.
Do not use after the expiry date.

Secure Disposal

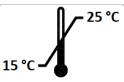
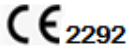
Each implant must be discarded after use and must never be reused. Implants that have encounter the patient, have been used, or have been removed from the patient during revision surgery should be considered medical waste and contaminated products.

When disposing of them, ensure that the discarded implants do not pose any threat to children, stray animals, or the environment. The disposal procedure is managed by hospitals in accordance with local regulations.

Feedback

Any professional (customer or user) encountering any abnormality in the services and/or quality, identification, resistance, reliability, safety, effectiveness and/or performance of INOVAMED products must inform INOVAMED or its authorized representative. This representative must report this claim to INOVAMED as soon as possible using an Incident Report.
If a fault or damage in the system or any abnormality in the user instructions causes deterioration in the health of a patient or user, please report it immediately by telephone or fax.
INOVAMED cannot be held liable for accidents resulting from failure to comply with the principles outlined in this Instruction sheet.

Symbols used on Label

	Do not re-use		Storage Conditions
	Manufacturer		Do not use if package is damaged and consult IFU
	Read IFU		Non-Sterile (Non Sterile prosthetic parts)
	Use-by Date		Caution
	Batch Code		Keep away from sunlight
	Catalogue number		Notified Body
	Date of Manufacture		Do not resterilize
	Sterlized using irradiation		Keep dry
	Medical Device		

For details on surgical procedures, please refer to the CK06 Surgical Guide.