Instruction for Use Implants

1.Product Description
Dental Implants are made of biocompatible titanium or titanium alloy. NOTCH Dental Implants contain a variety of surface treatments. Please refer to individual product labels for specific product description.

2. Purpose of Use
NOTCH dental implants;
The implant, which is the main part of the dental implant system, is known as the artificial tooth root. It effectively adheres to the jawbone with its sandblasted and hydrophilic outer surface. With the abutment connected with the help of an internal screw, the patient stays in his mouth for life.
Parts of Dental Implant Systems can be used to support and / or hold single member, multi-member or whole arch fixed and / or removable prostheses in partially or fully edentulous maxillary or mandibular arches.

3.Indications
- Complete and partial edentulous patients
- In jaw and face defects
- Complete tooth deficiencies with excessively resorbed crests
- For patients who have difficulty using removable partial dentures
- Fixed prosthesis patients with a very long gap
- In patients who refuse to use removable prosthesis
- In patients who do not want to have their teeth prepared
- In cases of serious changes in any toothless area or soft tissues where the full denture is seated
- In cases where oral muscular coordination is impaired
- In cases where tissue tolerance is low
- In patients with parafunctional habits that impair the stability of the prosthesis
- In patients with more expectations from full dentures
- In patients with excessive vomiting reflex
- In patients who psychologically oppose the removable prosthesis
- In the presence of insufficient number and location of support teeth
- In single tooth deficiency where neighboring teeth are healthy
- Trauma-related tooth loss or root fractures
- In the presence of internal granulomas
- In the presence of non-vital teeth with apical periodontitis that cannot be corrected by conservative methods or surgery
- External and internal root resorption
- For orthodontic anchorage purposes
- Dental agenesis
- Conservative treatment request (Request not to interfere with the patient‘s healthy teeth)

4. Contraindication
Recent myocardial infarction. The first thing to consider here is surgical stress. Because the adrenaline secreted during a surgical procedure will adversely affect the patient‘s cardiac condition. In addition, there may be uncontrollable vasoconstrictions, which may cause some disturbances in the heart rhythm. Since almost all of these errors use anticoagulant medication, a coagulation disorder may be present. There is also a risk against infections.
- Those with heart valve prosthesis. Likewise, there is a risk against surgical stress, coagulation imbalance and infections leading to the loss of the heart valve.
- Severe kidney disease. Here, calcium is not absorbed from the tubules. This causes metabolic loss of calcium. Parathyroid hormone malfunction. It causes metabolic osteopenia. Infection risk.
- Treatment of severe osteomalacia. (Rickets) There are hypophosphocalsic bone and osteoidosis. Inability to integrate the implant with the bone. 75% of rickets patients take vit D + Ca. This prevents integration. There is a risk of infection.
- Generalized secondary osteoporosis. Although primary osteoporosis is physiological, secondary generalized osteoporosis has pathological conditions such as Hodking‘s disease. Rarefaction is seen in the bone structure. Absence of osteodosis; Although there is a massive increase in the bone, there is a volume decrease. Integration of the bone with the implant does not occur. There is a risk of infection.
- Uncontrolled Diabetes Mellitus. Hyperosmolarity is seen in the blood. There are dehydration and metabolic diseases. Angiopathy: Most diabetics suffer from micro and macro angiopathy, which leads to a predisposition to tissue degeneration. There is a risk of infection. In addition, wound healing is difficult.
- Those undergoing radiotherapy. The defense mechanism is broken. Osteoindiction and osteoconduction are impaired. Physiological periosteal activity is impaired. There is a predisposition to tissue necrosis and a risk of infection.
- Chronic or severe alcoholism. There are liver diseases such as cirrhosis. These eventually lead to coagulation disorders. Medullary disorders (vit B1, B6, B12). As a result of these, there may be anemia, thrombocyte disorders, and risk of hemorrhage in different distant places. Delay in recovery occurs due to malnutrition. Psychological disorders. There is a risk of infection.
- Severe hormonal disorders. There is a metabolic calcium deficiency. There is a deterioration of the implant bed.
- Drug addiction. Pruritis sensation loss Nutritional disorder. Loss of resistance to diseases. Psychological disorders. There is a risk of infection.
- Long-term use of immunosuppressant drugs. Delay in recovery. Medullary aplasia. Increased bone fragility. Risk of infection
- Severe connective tissue diseases. For example, those that cause permanent damage to the connective tissue such as Lupus Erythematosus.
- Severe blood diseases. Diseases that cause structural disorders of the blood such as leukemia and hemophilia and affect the coagulation mechanism.

5. Warnings and Precautions
- The patient should be informed about the surgical risks before the operation and their positive and negative effects should be explained.
- The patient should be cautioned that the implanted device has a certain lifespan that cannot replace normal bone, may be damaged by strenuous activity or trauma, and may be replaced in the future.
- It is recommended to review the surgical technique specific to the product before performing the surgical procedure. NOTCH can provide surgical technical information. Please contact NOTCH sales representative.
- Correct selection of the implant is extremely important. The appropriate type is preferred depending on the age and activity levels of the patient, bone density, and whether or not he / she has undergone any previous surgical operation, considering the size of the largest component.
- NOTCH prostheses should be applied with breathing protection during oral use. Components or tools can injure the patient.
- Excessive bone loss or dental implant fracture can occur if an implant is overloaded beyond its functional capacity. Physiological and anatomical conditions can affect the performance of dental implants.
- Misuse of small components in the patient‘s mouth risks aspiration and / or swallowing.
- Forcing the implant deeper into the osteotomy than the depth created by drills may result in implant, driver, or osteotomy damage.
- For short implants, clinicians should monitor patients closely for any of the following conditions: Bone loss around the implant, changes in the implant‘s response to percussion, or radiographic changes of bone related to implant contact along the length of the implant. If the implant shows mobility or bone loss of more than 50%, the implant should be evaluated in terms of possible removal. If the clinician chooses a short implant, they should consider a two-stage surgical approach, attaching the short implant to an additional implant, and placing the widest fixture possible. The clinician should also wait longer times for osseointegration and avoid immediate loading.
- Reuse of NOTCH products labeled for single use may result in product contamination, patient infection, and / or device not performing as intended.
- It is recommended NOT to place implants with a diameter of less than 4 mm in the posterior regions.
- Dental Implant system components should only be used with their own system components.
- Implants should be placed in an appropriate diameter, in sufficient number and in an axis compatible with the dental arch.
- Drills suitable for the implant size and diameter should be used.
- Against the risk of contamination, when the implant is removed from the sterile package, it should be placed in the slot opened with the help of necessary equipment without touching the surface.
- Reuse of products labeled for single use may result in product contamination, patient infection, and / or device not performing as intended. Therefore, they are not suitable for second use after use.
- The product is for single use only. Do not use again.
- Check the expiry date of the product before using.
- Do not use the product if there is a foreign substance or contamination in the package or on the product.
- Do not use the product that has fallen to the ground.
- Since there is a risk of infection, dispose of the product as medical waste after use within the framework of legal procedures. NOTCH implant and prosthetic parts are available in a variety of configurations. Abbreviations are used in each product label to help.
- should not be opened.
- These devices should only be used by trained professionals. Surgical and corrective techniques required for the proper use of these devices are largely specific and complex procedures. Improper technique can result in implant failure, loss of supporting bone, fracture of the restoration, breathing, ingestion and / or digestion of loosened screws. When the clinician decides that adequate primary stability has been achieved, the immediate functional load option may be considered.
- The following factors should be considered when placing dental implants: bone quality, oral hygiene and medical conditions caused by blood disorders or uncontrollable hormonal disorders. The recovery period can be changed depending on the bone quality at the implantation site, the tissue response of the implanted device, and the patient bone density assessment performed by the surgeon during the surgical procedure. In order to avoid excessive force on the implant during the healing process, appropriate occlusion should be applied to the implant restoration.

6. Compliance Information
- Do not use implants from different metals and different manufacturers and accessories other than NOTCH together.
- NOTCH dental implant systems and surgical sets are compatible with each other.

7. Sterilization
NOTE: Sterilization materials with appropriate biological indicators should be used from the users you are sure of.
The implant is in sterile packaging. The products must be used sterile. The box cover should not be opened in any way before the use. The implant is sterilized using the Gamma Irradiation method.
DO NOT STERILE PRODUCTS AGAIN !!
Set parts are not sterile.

8. Storage and Transportation
The products should be kept in their original packaging. The product should not be used in case of damage to the tubing that maintains sterility. The products should be stored at a temperature of 25 + -5C, protected from direct sunlight. See labels for specific storage and transport rules.

9. Procedure
- Preparation of the implant bone should be performed with drills from the NOTCH surgical set at an operating speed of 400-900 rpm under copious irrigation. Care should be taken not to heat the bone. The use of out of sharp burs should be avoided. It can cause unnecessary trauma to the bone. The Surgical Technique Guide should be consulted for drilling.
- Check the length and diameter of the implant on the product label.
- There is a label on the product packaging to ensure traceability. Attach this label to the patient‘s file. Open the outer pack and empty the sterile inner pack into the surgical field.
- Use the NOTCH implant carrier to move the implant into the surgically prepared implant seat.
- NOTCH abutments are placed on the relevant implants with the help of an internal screw and a hand key. 30-35 Ncm torque is recommended for optimal connection between parts.
- NOTCH dental implant systems and surgical sets are compatible with each other.

10. Healing Process of Implants
In general, implants should be left to heal between 2-4, depending on the patient‘s bone quality, type and general health. Immediate and early loading can be accomplished with correct case selection and adherence to immediate loading protocols accepted in the literature. If immediate loading is to be performed, the initial torque of the implant should not be less than 35Ncm, the occlusion environment should be controlled, if there is more than one implant, it should be splinted, and in cases of complete edentulism, at least 4 implants in the mandible and six implants in the maxilla should be connected to each other with prosthesis.

11. MRI Safety Information
NOTCH Dental Implants have been found to be MR Conditional with tests performed in a non-clinical environment. Patients using this device can be safely scanned in an MR system when the following conditions are met:
- Static magnetic field of 1.5 T and 3.0 T
- Maximum surface area gradient of 3,000 gauss / cm (30 T / m)
- Average specific absorption rate (SAR) of the whole body in the maximum MR system 2 W / kg (Normal Operating Mode)

Within the scope of the scanning conditions described above, NOTCH Dental Implants are expected to increase the maximum temperature of 4 ° C at 3.0 T and 3°C at 1.5 T after 15 minutes of continuous scanning.
In non-clinical tests, the image artifact caused by the device expands radially up to 2.7 cm and 2.2 cm from the implant at 3.0 T and 1.5 T, respectively, when scanned with a gradient echo pulse sequence.

Manufacturerer
NOTCH Implant GmbH
Zum Schnüffel 6
58540 Meinerzhagen
Germany
www.notchimplant.com

Symbol Prepared According to EN 15223-1: 2012 Standard and Its Meanings

CE 2292	Notified Body number
	Caution
	Do Not Use Second time
	Please see instruction for use
	Producer Information
REF	Reference Number
MR	MRI Safety Information
NON STERILE	Non Sterile
LOT	Lot Number
	Batch Number
	Expiry Date
	Do Not Expose to Direct Sunlight
	Keep Away From Contact with Water
	Apply to corresponded documentation

Product Shelf Life Information
The product does not have a specified shelf life. The shelf life of the products is determined as 10 years with the support of the literature.

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