Ni2 Implant System
Product Description
The Ni2 Dental Implant System comprises dental implants, superstructures, instruments for prosthetics and surgical instruments. The Ni2 Dental Implant System is specially designed for use in dental implant surgery. A successfully osseointegrated implant will achieve a firm implant when surgically implanted under controlled and aseptic conditions, per well-known clinical studies. They are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations. The Ni2 Dental Implant System fixtures are made of commercial pure titanium, grade 4 (ASTM F67) which have a S.L.A (Sand-blasted Large grit Acid-etched) treated surface and supplied sterile (gamma radiation). These fixtures can be used as a one-stage surgery method or two-stage surgery method. They are surgically inserted into the upper and/or lower jaw bone. The fixtures replace tooth roots as providing a stable foundation for restorations. The fixtures have the diameter (3.0 - 7.0 mm) and length (8.5 - 15.0 mm). Geometrically, the implant is screw-type. An abutment is connected to the implant through a morse tapered-joint.

Intended Use/Indication for Use
Fixtures of Ni2 Dental Implant System are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients (e.g., tooth loss due to failing, tooth decay, tooth loss due to untreated cavities, and etc.). Fixtures can be placed with immediate function on single-tooth, bar and bridge applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants by the corresponding abutment components.

Contraindications
Customary observations should be made of the contraindications associated with implant materials used in oral surgery. First, the patient's general health and suitability for oral surgery must be assessed by the general practitioner by considering as follows:
- GENERAL CONTRAINDICATIONS
• insufficient bone quantity or poor bone quality endangering the primary stability of the implant
• acute or chronic infections
• subacute chronic osteitis of the jaws
• impairment of microvascular circulation
• systemic disease
• poor general health condition
• recent myocardial infarction
• immunosuppression
• active treatment of malignancy/cancer/tumors
• not completed maxillary or mandibular growth
• allergies or hypersensitivity to chemical ingredients of materials used

- RELATIVE CONTRAINDICATIONS
• addictions (alcohol, tobacco, drugs)
• inadequate oral hygiene, lack of motivation, lack of cooperation
• diabetes mellitus
• head and neck radiation
• postmenopausal and hormone replacement therapy
• osteoporosis, e.g. intravenous bisphosphonate use
• psychiatric illness
• use of anticoagulation drugs / hemorrhagic diathesis
• pregnancy
• preterm infants and neonates
• infants and children: not before the jaw bones have stopped growing (in general 17-18 years).

- LOCAL CONTRAINDICATIONS
• uncontrolled parafunctional habits
• insufficient height and/or width of bone
• insufficient inter-arch space
• intraoral infection
• local root remnants

Warnings
Implant surgery and restoration involve complex dental procedures which require specialized training. Training is strongly recommended prior to implant use. Improper technique and/or improper patient selection can result in implant failure and/or loss of bone around the implant site.

Precautions
Thorough screening of implant candidates is critical to the success of the implant process. Appropriate radiographic examination should be utilized to determine adequacy of bone, periodontal status, and the location of important anatomical landmarks. Post-implantation radiographs are also required to determine the progression at osseointegration. Exposure to magnetic resonance imaging, radiation, and chemotherapy may impact the health of the implant. Dental implant patients should be instructed to consult with their dentist or oral surgeon prior to undergoing such treatment options. The use of electro surgical instruments or lasers around the titanium implants and their abutments is not recommended due to the risk 01 electrical shock and or burns.

Adverse Effects
There were major perioperative complications in related literature(s) and/or equivalence device(s) as follows:
- Screw loosening
- Peri-implantitis
- Implant fractured
- Implant lost
- Inflammation/Hyperplasia
- Gingival recession
- Bone resorption
- Improper Osseointegration

Please note the following precautions:
According to federal law, the sale of this device is restricted to dentists or oral surgeons. Ensure the fixture vial remains open with the cap upwards to secure the fixture in place for attachment to the Implant Driver. Detailed instructions regarding the surgical procedure can be found in the Surgical and Prosthetic Manual. The product is gamma sterilized and remains sterile as long as the packaging remains unopened and undamaged. Do not use the product if the packaging is damaged or opened. Do not use beyond the stated expiration date. This product is intended for single use only and should not be resterilized. Opened, unused products cannot be returned to the company.

Delivery, Storage and Handling

Outer Box : NON-STERILE
Blister Packaging : STERILE
Outer Vial : STERILE
Inner Vial : STERILE
Implant : STERILE

Store the product in conditions where it is not exposed to direct sunlight or extreme temperatures (between 1°C and 30°C). When opening the product, use aseptic technique to prevent contamination, ensuring that the correct size has been determined before implantation. Handle the fixture with care to avoid damaging its surface. Additional product labels containing the LOT number and REF number are provided with the fixture. These labels should be placed in the patient's chart and medical records to ensure complete traceability of the implant for future reference or inquiries.

Instructions for Use (Surgical Procedure)

Caution: The Ni2 Implant System fixtures can be inserted using a one or two-stage procedure. One-stage implantation should only be considered for patients with good bone quality, proper oral hygiene, appropriate personal habits (non-smoker, no alcohol or drug abuse), and where there is the ability to obtain good initial stability of the implant (>35-45 N.cm).

Before implantation, a complete health evaluation, oral examination, and radiological assessment should be conducted for successful implant treatment. All surgeries should be performed under aseptic conditions using sterile surgical instruments.

First Stage Implant Surgery
1) Incision and flap resection
2) Drilling Sequence (Refer to Surgical and Prosthetic Manual for specific instructions) => Guide Drill and 2mm first Drill-1000rpm/30-45 N.cm with irrigation
=> Check drill path- Verity drilling path using the Parallel Pin and Depth Gauge
=> Pilot Drill and Final Drill- 1000rpm/30-45 N.cm with irrigation
=> Counter Sink (Optional-1000 rpm/30-45 N.cm with irrigation)
Warning: During drilling, irrigate to prevent bone overheating. Overheating can lead to bone damage, resulting in failure to ossify and potential loss of the fixture.

3) Fixture insertion
Caution: When opening the fixture cap, hold the fixture container upright and engage the Implant Driver into the fixture, connecting them firmly together. Remove the fixture from the packaging and attach it to the implant driver. Insert the fixture into the bone, turning clockwise at 20rpm/35N.cm with irrigation using the Implant Driver. It is recommended that the top level of the fixture be located 0.5mm below the crestal bone. Place a label identifying the LOT number and REF number of the fixture in the patient's chart to ensure traceability to the implant used.

Warning: Applying excessive torque (more than 80N.cm) may result in fracture or damage to the bone.

4) Cover Screw or Healing Abutment Application
Thoroughly clean blood and fluid from the fixture interface before attaching the cover screw or healing abutment. Failure to properly clean the fixture can lead to difficulty in removing the cover screw or healing abutment.

For two-stage procedures, use the hex driver to apply the cover screw. For one-stage procedures, use the hex driver to apply the healing abutment.

5) Soft tissue suturing
The healing period after the first-stage surgery depends on the patient's bone condition and quality. Radiographs are necessary before surgery to assess the bone condition, and again after the second-stage surgery, as well as before loading the implant. To prevent movement at the fixture and potential implant loss, prosthetic loading should only be carried out once there is evidence of implant osseointegration.

Second Stage Surgery (following application of the cover screw)
1) Incision and removal of the cover screw (unscrew in a counterclockwise direction)
2) Apply healing abutment using the hex driver.
3) Soft tissue suturing

Impression and Restoration Fabrication
Warning: Before loading on to the fixture, confirm evidence of osseointegration through radiographic examination to prevent fixture movement and potential loss of the implant.

Caution: Ni2 Implant System fixtures are designed exclusively for use with Ni2 Implant System Instruments, Abutments, and Components.

Newton Implant Systems, inc
www.Newtonimplant.com

Catalogue code


Do not Reuse

Not Sterile


Date of Manufacture

Lot Number


Manufacturer


Keep away from direct sunlight

Prescription Only

Medical Device

Do not use if packaged is damaged

Instruction for Use