User Instructions

Description: NOVA® Dental Implant System consist of root form dental implants of various lengths and diameters, abutments, additional superstructures and surgical components, which provide the clinician with cement retained, screw retained restorative options. The implants and abutments are made out of Ti6Al4V Titanium alloy.

Indication for Use: NOVA® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. NOVA® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Direction for use: The implantation procedure should be done under aseptic conditions with specifically designed sterile surgical instruments, an electrical surgical drilling system with internal and external irrigation is recommended for drilling the surgical site. Specific drilling sequences for placement of implants should be followed. For detailed information on the specific product system you are using, please consult the NOVA® IMPLANTS catalogue & surgical manual. Use Latex free gloves to prevent allergenic reaction

Contraindications: General contraindications associated with elective surgery should be observed. Possible contra indications: chronic bleeding problems, psychological impairment, metabolic bone or connective tissue disease, treatment with corticosteroids, certain cardiac and vascular diseases, tobacco usage, diabetes (uncontrolled), treatment with chemotherapeutic agents, chronic renal disease, poor patient oral hygiene, bruxism, alcoholism.

Possible contraindications: Poor oral hygiene, bruxism, alcoholism, smoking, drug abuse, psychological problems, aggressive behavior.

Temporary contraindications: Systemic infection, local, oral or respiratory infection. Anatomical or pathological contraindications: insufficient alveolar bone width and height to surround the implant with at least one millimeter of bone, both buccally and lingually to the most superior aspect of the implant body; inadequate bone height where proper implant placement would encroach on the mandibular canal; malignancies.

Storage and Handling: Devices should be stored at room temperature. Refer to individual product labels and the Surgical Manual for special storage or handling conditions.

Warnings: Excessive bone loss or breakage of a dental implant or restorative device may occur when an implant or abutment is loaded beyond its functional capability. Physiological and anatomic conditions may negatively affect the performance of dental implants. The following should be taken into consideration when placing dental implants:

- Poor bone quality
- Poor oral hygiene
- Medical conditions such as blood disorders or uncontrolled hormonal conditions

It is recommended that small diameter implants not be restored with angled abutments in the molar region. Mishandling of small components inside the patients mouth carries a risk of aspiration and/or swallowing. Forcing the implant into the osteotomy deeper than the depth established by the drills can result in: stripping the driver hex interface inside the implant, stripping the driver, cold welding of the mount-driver interface to the implant, or stripping the walls of the osteotomy that may prevent an effective initial implant fixation. The NOVA Dental Implants System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of NOVA Dental Implants System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Patient information: Preoperative examination and get an explanation about the treatment, including the expected results of the risks. Patients should sign informed consent their acceptance treatment. Patient status information should be registered, such as general medical contraindications, the surgical treatment, mental psychoses, alcohol and all of the information mentioned above.

Precautions: The surgical techniques required to place endosseous dental implants require specialized and complex procedures. Formal training for placement of implants is recommended.

Important: determine local anatomy and suitability at the available bone for implant placement. Adequate radiographs direct palpation and visual inspection of the implant site are necessary prior to treatment, planning and use of NOVA IMPLANTS.

Sterility: NOVA IMPLANTS dental implants are gamma sterilized. Do not re-sterilize. Do not use if package is opened, damaged or expired. Discard open, unused product. Re-use of implants can lead to serious problems of infection and bone re- sorption and can cause damage to hard and soft tissue. Therefore re-use is strictly forbidden.

Procedural Precautions, Surgery: During the planning phase, it is important to determine the vertical dimension, the actual space available between the alveolar crest and the opposing dentition, in order to confirm that the available space will accommodate the proposed abutment and the final crown restoration. This information varies with each patient and abutment; therefore it should be carefully evaluated before placing any dental implant. The final prosthesis should be designed prior to the placement of the dental implant. Utilize continuous irrigation with a cool, sterile irrigating solution to avoid excessive damage to the surrounding tissue and to prevent compromising Osseo integration. This is mandatory during all procedures. Avoid excessive pressure during preparation of the bone site. Only sharp instruments of the highest quality should be used for any surgical procedure involving bone. Minimizing trauma to the bone and surrounding tissue enhances the potential for successful Osseo integration. In order to eliminate contaminants and other sources of infection, all non-sterile devices should be cleaned and/or sterilized prior to use, per the instructions on the individual product labels.

IMPORTANT WARNING! Lack of adequate training of practitioner is a major risk factor for the success of the implant procedure and might endanger patient health. No implant shall, therefore, be performed without prior adequate training by a Certified Institute.

Procedural Precautions, Restoration: The Dental Abutments System is provided non sterile. Prior to use, these must be sterilized in an autoclave by gravity displacement, in compliance with the manufacturer's instructions; Use single pouch at 121°C for 30 minutes, drying time 30 minutes.

The validated procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79:2010.

The healing period varies depending on the quality of the bone at the implantation site, the tissue response to the implanted device and the surgeon's evaluation of the patient's bone density at the time of the surgical procedure. Excessive force applied to the dental implant should be avoided during the healing period. Proper occlusion should be evaluated on the implant restoration to avoid excessive force.

Potential Adverse Events:

Potential adverse events associated with the use of dental implants may include:

- Failure to integrate
- Loss of integration
- Dehiscence requiring bone grafting
- Perforation of the maxillary sinus, inferior border, lingual plate, labial plate, inferior alveolar canal, gingival
- Infection as reported by: abscess, fistula, suppuration, inflammation, radiolucency
- Persistent pain, numbness, paresthesia
- Excessive bone loss requiring intervention
- Implant breakage or fracture
- Systemic infection
- Nerve injury

Techniques:

- Determine local anatomy with the use of local X-rays and CT. etc.
- Planning the site, the technique and the dimensions of the implant to be used.

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a licensed dentist or physician.