INSTRUCTIONS FOR USE - DENTAL IMPLANTS

Manufacturer
Ritter Implants GmbH & Co.KG
Freiburger Str. 45
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Product Description:

Ritter Implants GmbH & Co.KG (hereinafter: the Company) implants manufactured of Titanium alloy (Ti6Al4V ELI) and are provided sterile (Gamma irradiation sequence, Cobalt 60 source) for single/single patient use.

Indications:

The implants are intended for surgical placement in the upper or lower jaw, for supporting the single or partially edentulous Mandibular and/or Maxillary Alveolar process. The implants are appropriate for immediate loading when sufficient primary stability is achieved along with appropriate Occlusal loading.

Recommendations:

- An essential stage, prior the implants placement, is to verify the satisfactory quantity and quality of the bone.
- It is also vital to verify and make sure that the anatomic areas near the implantation site (such as: blood vessels, nerves, maxillary sinus, and nasal cavity) are properly identified, to prevent accidental damage.
- The Company recommends using of following torques for implants placement:
- In case of immediate loading it is recommended to place the implants using torque of at least 35Ncm.
- All other cases it is recommended to use the torque up to 50Ncm

Note: The performance of surgical procedures is subject to Patient systemic conditions. The decision of torques is to be taken upon the evaluation of the bone quantity and quality by dental Practitioner, performing the procedure.

⚠ **Contradictions:**

Cardiovascular disorders associated with high endocarditic risk, Coronary insufficiency, Cancers and radiation of the facial region in the past five years, Systemic or uncontrolled local diseases, Respiratory diseases, Thyroid/parathyroid disease and Patients with nodular enlargements, or inexplicable lumps in the head or neck region, Hypertension above 170/110 mmHg, Fibrous dysplasia, Use of Prophylactic antibiotics, Patients on corticosteroids, anticoagulants, anticonvulsive, and immunosuppressant therapy, Organ transplanted Patients, Granulocytopenia, Patients with abnormal values for creatine, BUN, or serum calcium, Weakened immune system, Diabetes, Bone metabolism disorders, Hemophilia, Ehler-Danos syndrome, Poor general state of health, Inadequate wound healing capacity, Maxillary and mandibular growth not completed, Unfavorable anatomic bone conditions, Periodontal disease, Poor oral hygiene, Bruxism, Inadequate bone or blood supply, Unrealistic Patient expectations or poor Patient

motivation, Psychological disorders, Smoking, Drug abuse or alcoholism, Steroid use, Allergy to metals (Titanium, Aluminum, Vanadium and tec.,)

Warnings

- Carefully read the instructions, prior to implants use;
- The sale and use of the implants are restricted to, or by the order of licensed dental Practitioner (or dental prosthetic Specialist, for abutments meant for laboratory use);
- Implants should be placed only by Practitioners who are licensed and trained to perform the procedures. Adequate preoperative studies are recommended - to examine the anatomic structures and to assess the biomechanical, functional, and esthetic requirements of each case;
- Risks of implants placement include, but not limited to infection, dislodgement of the implants, damage to adjacent teeth, and fracture of implants or restorative component;
- Each implant has a specific design characteristic to mate the implant, prosthetic components, and designated instrumentation. It is recommended that the Performers of the procedures be thoroughly familiar with the system;
- The implants have not been evaluated for safety and compatibility in the MR environment;
- The implants installation procedure requires a high degree of precision and care. The Performer must be properly trained and skilled in required processes and procedures;
- The implants provided sterile and ready for use;
- ***The implants re-processing (re-sterilization) is strictly forbidden.***

Post operation instructions for Patients:

Warnings

- Avoid any activity may cause physical stress post implantation procedure;
- Consume (eat) only cold, soft food;
- As per the instructions by Practitioner take antibiotics, use oral rinses and analgesics;
- Do not spit or brush the teeth at the day of the procedure;
- Use ice pack (if needed) on the ***external*** area of implantation on the day of procedure.

Post operation effects:

- Short-term – pain, swelling, bleeding, hemorrhage.
- Short-term complications and risks – nerve damage causing temporary loss of sensation of the lower lip and/or tongue, damage to blood vessel (may cause life-threatening bleeding), perforation to nasal cavity and/or maxillary sinus, local or systematic infections.
- Long-term complications and risks – nerve damage causing permanent loss of sensation of the lower lip and/or tongue, chronic pain, local or systemic infection, damage to adjacent teeth, fracture of bone, esthetic disorders and infectious endocarditis.

Warnings

Patient should be instructed to seek immediate attention of the Practitioner in case of any complications.

Sterility:

Implants and cover screws – provided sterile and ready for use. These components are for single use (single Patient).

Warnings

- The implants should be used prior their expiration date (post expiration use of implant is strictly forbidden);
- Use of implant with damaged package or package been previously opened – strictly forbidden.
- Implant re-processing (re-sterilization) is strictly forbidden.

Storage:

The implants shall be kept in their original package, in a dry place at room temperature.

Limited warranty:

In case of failure of an implant, the Company will replace/provide another implant in exchange free of charge, according to following conditions:

- Filling in a report with all the information concerning the failure, including any relevant supporting information;
- Submitting the report, no later than 6 months from the event;

Labelling:

Caution / Attention: See Instructions for Use	Do Not Reuse	Expired by	Manufacturer	Lot Number	Authorized Representative in the European Community	Do Not Use If Package Is Open or Damaged	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician	Catalog Number	Number of units	Sterilized using irradiation	CE Mark	Non-Sterile