

General Instructions for use and Warnings: Odontit Implant Systems

Product description

The **Odontit Dental Implant System** is an integrated system of endosseous dental implants with corresponding abutments, healing abutments, closure screws and surgical and prosthetic parts and instruments.

Intended use

The **Odontit Dental Implant System** are suitable for the treatment of oral endosteal implantation in the jaw and for the functional oral rehabilitation of edentulous and partially edentulous patients.

Contraindications

Non-completed jaw bone growth, drug or alcohol abuse, allergies or hypersensitivity to chemical ingredients of materials used: titanium, all conditions which would be normally contraindicated for oral surgery.

Side effects, precautions & complications

Immediately after the insertion of dental implants, activities that demand considerable physical exertion should be avoided. Information related to side effects, interactions and precautions, complications with implants should be provided to the patient. Possible complications following the insertion of dental implants are:

Temporary symptoms

Pain, swelling, phonetic difficulties, gingival inflammation.

More persistent symptoms

Chronic pain in connection with the dental implant, permanent paresthesia, dysesthesia.

Warning

Products must be secured against aspiration when handled intra-orally. Aspiration of products may lead to infection or unplanned physical injury. Avoid approaching the proximity of the mandibular nerve channel during implant bed preparation and implant insertion. Nerve damage may result in anesthesia, paresthesia and dysesthesia. Do not exceed recommended insertion torque as this might cause bone necrosis.

Caution / Precautions

Particular care should be taken to assure proper implant alignment where comparatively high loads are expected. Small-diameter implants are not recommended for the posterior region. Inadequate bone volume and/or quality might lead to insufficient primary stability and consequently mobility and even loss of the implant. Avoid corrections of the vertical position using reverse rotations. This may lead to a decreased primary stability. Sterile handling is essential. Never use potentially contaminated components. Contamination may lead to infections. Special patient conditions like diabetes, bruxism, tobacco abuse, bone metabolic disorders (e.g. osteoporosis), irradiated patients, pregnancy could lead to reduced success and survival rates of the implants and therefore need a careful assessment by the responsible surgeon and information to the patient. **Odontit Dental Implant System** have not been evaluated for safety and compatibility in the Magnetic Resonance environment.

Storage

The implants must be stored in a dry place in the original packaging. Protect from direct sun light and at room temperature (**5° to 25 ° C**). Improper storage may compromise essential material and design characteristics leading to device failure. Do not re-sterilize **Odontit dental implants**. Do not reuse Odontit dental implants. Reuse of single use devices creates a potential risk of patient or user infections. Do not use Odontit dental implants after expiry date indicated on the packaging. Use of Odontit dental implants after expiry date might lead to infections.

Cleaning and Disinfection

Odontit dental implants are provided sterile and for single use only. They must not be cleaned and sterilized. Cleaning, disinfection and sterilization may compromise essential material and design characteristics leading to device failure.

Sterilization

Odontit dental implants are delivered sterile by Gamma irradiation. The intact sterile packaging protects the sterilized implant from outside influences and, if stored correctly, ensures sterility up to the expiration date. When removing the implant from the sterile packaging, rules of asepsis must be observed. The sterile packaging must not be opened until immediately prior to insertion of the implant. Implants with damaged sterile packaging must not be used. It is recommended to have a replacement implant at hand. Odontit does not accept any responsibility for re-sterilized implants, regardless of who has carried out re-sterilization or by what method. A previously used or non-sterile implant must not be implanted under any circumstances.

For more information consult instructions for use for each product and Odontit Manual. Please follow the link to the e-IFU: www.odontit.com