

Summary of Safety & Clinical Performance Of ITL Dental Implant System

ITL Dental is the manufacturer of a dental implant system which intended use is to replace missing, and/or compromised natural teeth including the tooth (crown), which is above the gumline, and the root which anchors to the tooth (crown). As dental implants contain a crown and a titanium root as a replacement, the patient will have a complete and stable replacement for their missing/compromised teeth. The sterilized titanium alloy implant is screwed into the patient's jaw-bone enabling the bone to fuse around the implant for stability. This process, called integration, usually takes 3-6 months. Once the healing is complete the dental practitioner places an abutment on the implant and eventually a crown will be placed for the final restoration. Patients may choose to have just one implant or replace as many as advised by a licensed dental practitioner who has received adequate dental restorative surgical and/or prosthetic training.

The licensed dental practitioner must determine patient's suitability for implants by considering the patient's health. Impairments such as vascular conditions, uncontrolled diabetes, metabolic bone disease, chemo and/or radiation therapy, chronic periodontal inflammation, insufficient soft tissue, heavy smoking which could cause gum disease, and/or mouth cancer, and use of prescription medicines which may contradict the patient's ability to heal, may make a patient not eligible for dental implantation. Additionally, the patient's bone condition may be a risk factor as well as bruxing, clenching, gnawing of their teeth day or night. Other issues, such as the possibility that a patient may be allergic to the titanium alloy implant and abutment, and/or other accessories such as the stainless steel instruments used during the procedure, may jeopardize the successful implantation. It is important that the patient share with the dental practitioner any known allergies, illnesses, and behaviors which may impact the success of the procedure.

The dental practitioners should pay attention to the negative and positive usage of titanium dental implants per each patient, and need to be aware of the problems that may arise after the implantation, and should be able to diagnose any issues disclosed by the patients, in spite of very rare occurrences of negative reactions.

Abutments, healing caps and other ITL Dental accessories are not sold sterile and it is up to the dental practitioner to sterilize (i.e. autoclave), the devices prior to use. Implants must be stored in a dry place, at a controlled temperature, in their original packaging. Dental implants are provided in sterile vials affixed to fixture mounts. The plastic cap attached to the fixture mount is intended to be used to transport the implant to the prepared surgical site. Do not handle implant surfaces directly. Users are advised to visually inspect the package to ensure seals and contents are intact and in their original packaging prior to use.

During the pre-operative stage, availability of bone-height and width must be determined. Appropriate radiography should be used to determine bone availability, optimal implant location and to avoid structures such as the mandibular canal, maxillary sinuses and adjacent teeth. Electro surgery: Due to the conductive nature of metallic implants, electro surgery is contraindicated. Post-surgery requirements will be determined by the licensed dental practitioner and should be followed closely by the patient to protect from rejection, infection and/or any other negative reactions.

Device Safety is important to ITL Dental who designs and manufactures the dental implants and restorative components which are part of the system, according to applicable US, EU and other applicable International standards. The titanium alloy dental implants, abutments and healing caps are fatigue tested and bio assessed which prove them to have exceptional strength and biocompatibility. ITL Dental's implant system has been on the market for over 15 years without any safety and performance issues that has caused any patient harm. ITL Dental provides the part and lot numbers of its implantable devices so that patient information can be maintained in the patient's chart.

With proper dental hygiene and regular checkups, as suggested by the licensed dental practitioner, it is possible that the implants could last a lifetime, which is not always the case for bridges, partials, or crowns over broken teeth, therefore implants are a reasonable and safe choice when a patient requires teeth replacements.