SURCAM
Dental Pro.

Instructions For Use for Dental Implants

Description:
The Surcam's Dental Implant System consist of rootform 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 and have an internal anti-rotational geometry.

Indications for Use / Intended Use:
The Surcam's Dental Implant System is intended for surgical placement in the maxillary and mandibular arch, to support crowns, bridges, or over dentures, in edentulous or partially edentulous patients. It is intended to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. The System is intended to be used in either single tooth or multiple teeth applications. The prostheses can be screw or cement retained to the abutment. The Surcam's Dental Implant System may be placed immediately and put into immediate function provided that initial stability requirements are satisfied.

Directions for Use:
The implantation procedure should be done under aseptic conditions with specially designed sterile surgical instruments, an electrical surgical drilling system with internal or external irrigation is recommended for drilling the surgical site. Specific drilling sequences for placement of implants should be followed. The maximum insertion torque is 50 Ncm.

Warning:
Improper technique can contribute to implant failure and loss of bone. Surcam's Dental Implants are intended for use only in the indicated applications. Dental Implants must not be altered in any way. The use of electro-surgical instruments or lasers around metallic implants and their abutments is not recommended due to the risk of electric and heat conductivity. Implant mobility, bone loss, or chronic infection may indicate implant failure. Surcam's dental implants are gamma sterilized. Do not re-sterilize. Do not use if package is opened, damaged or expired. Discard open, unused product. Do not re-use. Repeated use of implants can lead to serious problems of infection and bone resorption and can cause damage to hard and soft tissue. Therefore, re-use is forbidden.

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

Important:
Adequate bone to support the implant with width and height being the primary dimension of concern. The obligatory bone dimension for implant placement in a desired site may be determined using radiological techniques. Also a careful evaluation has to be made of the location of vital blood vessels, maxillary sinus, soft tissue spaces and their relation to planned site for implant placement.

Adverse Reaction:
Some complications that can occur include: infection, bone loss, patient discomfort, implants mobility, local soft tissue degeneration, and unfavorable implant placement or alignment. Additional information and steps to be taken can be found in the Surgical Manual.

Risks associated with surgical procedure fall into four broad categories:
1. Immediate anesthetic and surgical risks.
2. Psychological and psychiatric risks.
3. Medical threats to long-term retention.
4. Long-term deleterious effects of implants on health.
The potential risks are: inadvertent perforation of the nasal and maxillary sinus, local and systematic infections, perforation into soft tissue spaces; nerve injury. Temporary conditions that may result from implant placement include pain and swelling, speech problems, gingivitis. Long-term problems may include nerve, local or systematic bacterial infections, and infectious endocarditic in susceptible individuals, including those with body part replacement. Existing natural dentition may be compromised by improper implant placement.

Residual risks:
One hundred percent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may cause undesirable results. Error in recognition of the actual drills lengths relative to the radiography can result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to hemorrhage in the floor of the mouth.
Treatment by means of implants may lead to loss of bone, biological and mechanical failures, including fatigue fracture of implants. Close cooperation between surgeons, restorative dentists and dental laboratories technician is essential for successful implant treatment.

Contraindications and risks:
The conditions listed below may contribute to lack of integration and/or subsequent implant failure.
Absolute contraindication to implantation.
This implies the presence of diseases and certain conditions of the body when surgery is an obvious health risk, as well as when there are non-treatable diseases that make it impossible to achieve positive results of implantation. These include:
• Chronic diseases in the stage of decompensation (weakened immune system, serious internal medical problems and et.).
• Systemic disorders of coagulation (bone metabolism disturbances).
• Uncontrolled bleeding disorders.
• Immunodeficiency, AIDS and any other seropositive infection.
• Psychological instability or diseases (uncooperative or unmotivated patient).
• Psychiatric disorders that interfere with patient understanding, compliance with required procedures.
• Drug or alcohol abuse.
• Allergies or hypersensitivity to chemical ingredients of materials used: in case of known allergic reactions to metallic part, a preliminary test is recommended.

Relative contraindication or risk factor:
Unless augmentation can be considered, the implants should not be placed if insufficient alveolar bone volume could support it (minimum 1mm circumferential, 2mm apical).
Implants placed in the maxilla should not perforate the sinus floor membrane.
Surgical intervention represents an obvious health risk. However, relative contraindications are only diseases that create certain difficulties for achieving the predicted result, statistically reduce the effectiveness of implantation and can lead to unsuccessful treatment.
Risk factors include unfavorable anatomical conditions of hard and soft tissues of the jaws, that require additional surgical interventions or non-standard approaches to treatment.
Other risk factors are: irregular lifestyle, patient's age, intellectual level and emotional status, acute and chronic diseases in the compensation stage, pathologies with homeostasis stabilized or compensate, changes in the organs and systems of the body due to modern methods of treatment. These include:
• Patients whose implantation site are under osteolytic, inflammatory or infectious activity.
• Abnormal laboratory values for BUN, creatinine, or serum calcium.
• Patients with hypertension above 170/110 mm Hg;
• Patients with respiratory, chronic obstructive pulmonary disease COPD.
• Acute inflammatory diseases and acute viral infections, oral infections.
• Chronic infectious diseases (tuberculosis, actinomycosis, etc.).
• Chronic diseases in the stage of compensation.
• High risk of bacteremia (patients with prosthetic heart valves and endured bacterial endocarditis, rheumatism).
• Patients with cardiovascular and lung diseases, especially those who only recently suffered heart attack or stroke; coronary artery disease, arrhythmias.
• Pregnancy and lactation.
• Gastrointestinal, hepatitis, malabsorption, inflammatory bowel disease.
• The heavy consumption of tobacco is associated with the increase in the loss of dental implants; failure rate around 2.5 times higher in patients who smoke is reported.
• Treatment with drugs that worsen the tissues regeneration (immunosuppressant, hormonal, corticosteroids, anticonvulsant, prophylactic antibiotics, anticoagulation therapy, etc.).
• Patients with diagnosed malignant neoplasms in the past five years or unexplained lumps or masses in the head or neck as well as nodular enlargements: exposure to radiation, chemotherapy or other immunosuppressive therapy may impact the implant health.
• Young people under the age of 21 years.
• Arthritis, osteopathic diseases that adversely affect osteogenesis, osteoporosis-reduction of total bone tissue, osteomalacia - inadequate mineralization of the organic bone matrix with a normal skeletal mass and bone volume.
• Uncontrolled systematic diseases that disrupt osteogenesis: diabetes mellitus, brittle diabetes, thyroid or parathyroid gland and pituitary/adrenal diseases, adrenal gland pathology, blood diseases such as hemophilia, granulocytopenia or other bleeding problems; Ehler-Danlos syndrome, osseo-radio necrosis, renal failure, organ transplantation, fibrosis dysplasia, regional enteritis.
• Alcoholism and drug addiction cause not only mental changes, but also a number of somatic disorders affecting osteogenesis.
• Systemic connective tissue diseases: systemic lupus erythematosus, dermatomyositis, Siegen's syndrome, a group of congenital systemic connective tissue diseases inherited in an autosomal dominant pattern: Kind, Gurley, Meknes syndrome, Gautier's disease, Niemen-Pick syndrome, various types of congenital dysplasia and dysostotic.

• Application of medications reducing blood clotting by patients, anemia, leukemia, etc.
• Pathological conditions of maxillofacial area and oral cavity: leukoplakia, stomatitis, caries, xerostomia, periodontitis, macroglossia, malocclusion, jaw deformity temporomandibular joint diseases, gingivitis, periodontitis, peri-implantitis, and unsatisfactory oral hygiene.
• Severe bruxism, clenching, and overloading, may cause bone loss, screw loosening, component fracture, and/or implant failure.
• Patient's inability to maintain oral hygiene.
• Poor patient motivation, retardation, mental disorders that interfere with the patient understanding and compliance with the necessary procedures. Unrealistic expectations. Unattainable prosthetic reconstruction. Hypersensitivity to a specific component of the procedure.
Treatment of these diseases should be carried out in parallel with implantation, or implantation can be regarded as one of the ways of treatment. If no we can get peri-implantitis, microsites or losing the implant.

SMOKING SIGNIFICANTLY REDUCES THE RATE OF SUCCESS.

Possible Undesirable Side Effects:
The implant placement is an invasive treatment which may be associated with typical side effects such as bleeding, short- term swelling and bruising of the gums and face, local pain, Infection, injuries to the nerve, jaw fracture or allergic reaction to chemical ingredients of material used (Titanium Alloy Ti6Al4V ELI).

Potential Complications:
Rejection of the implant - due to the failure of the jawbone to osseointegrate with the implant.
Infection at the implant site - may be caused due to poor oral hygiene. Tissue Injury, Damage - the affected area usually swells temporarily, but returns to normal within a few days. The patient has to report any longstanding swelling.
Nerve injury - caused due to placement of the implant too close to the nerve or over the nerve. The dentist may remove the implant (if necessary) and replace it.

Important Warning:
Lack of adequate training of practitioners IS 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.

Sterility-Implants:
Surcam's 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.

Limited Warranty:
In case of implant failure, Surcam undertakes to replace such implant unit, free of charge, Subject to the following conditions: A written notice of such failure is submitted to Surcam, not later than within 6 months of first sign indicating such failure, accompanied by a follow-up report in the form issued by Surcam, the relevant X-Ray and the failed implant. This is the complete warranty for the implant by Surcam, setting forth your exclusive remedies respecting thereto. For more details on the handling of the Surcam dental implants system, refer to Surcam Catalog.

Caution:
Federal (USA) law restricts this device to sale by or on the order of a licensed dentist or physician. Surcam has not been evaluated for safety and compatibility in the MR environment. Surcam has not been tested for heating or migration in the MR environment. Do not reuse Implants, Cover screws, and Abutments. Re-use of these items, leads to an increased risk for product failure as functionality cannot be guaranteed if these products are reused. In addition, there is an increased risk of contamination.

How Supplied:
The sterile package contains one dental implant including cover screw, Abutments, superstructure, surgical tools are supplied non-sterile.

MR conditional:
Non-clinical testing has confirmed that the Surcam dental implants, abutments, and prosthetic screws are MR conditional. A patient with these devices can be safely scanned in a MR system meeting the following conditions:
• Static magnetic field: 1.5 Tesla and 3.0 Tesla only.
• Maximum spatial gradient magnetic field: 3000 Gauss/cm (30 T/m).
• RF Excitation - Circularly Polarized.
• RF Transmit Coil Type - no Transmit Coil restrictions.
Maximum MR system reported, head-specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or whole body averaged specific absorption rate (wbSAR): 2 W/kg.
Scan Duration: 2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks).
• MR image Artifact: The presence of this implant may produce an image artifact.
Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the Implantable Device. The SSCP can be received upon request at the Surcam Dental Ltd email address: sales@surcamdental.com

Symbolic Information:

REF	Catalog Number
LOT	Batch Code
	Manufacturer
	Date of Manufacture
	Use by date
STERILE R	Sterilization using Irradiation
	Do not re-use, Single use
MR	MR conditional
	Keep away from sunlight
	Keep dry
	Do not re-sterilize
CE	Notified Body
EU REP	Authorized EU Representative
	Consult accompanying documents
	Do not use if package is opened or damaged
Rx only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Single sterile barrier system with protective packaging inside
MD	Medical device
	Importer
	Information website for patients

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