SURCAM
Dental Pro.

Instructions For Use for Abutments & Prosthetic components

Description:
The Surcam's Dental Implant System consist of root form dental implants of various lengths and diameters, abutments, additional superstructure 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.
The restorative abutments have a hex connection which engages the S-type and C-type implants internal hex. The abutments are available in multiple cuff heights in straight and offsets in 15º, 25º, 35º and 45° angulated configurations to provide correction for off-angle implant placement. The abutment is secured to the implant with a retaining screw which is preassembled in the abutment. The screw is not removable from the abutment. The abutment has an internal screw access for the attachment of various restorative components using a separate coping screw. Abutments are packed with a screw in a plastic bag or tube. The abutment and its retaining screw are fabricated from titanium alloy.

Indication for Use / Intended Use:
Surcam Abutments are prosthetic components directly connected to the endosseous dental implant to provide support to prosthetic restorations such as crown, bridge and overdentures in partially or fully edentulous patients.

Location in the Mouth:
• Straight - Located in all the sectors of the mouth.
• Angled - Located in the anterior sector of the superior maxilla (upper jaw) for 25º angled abutments.
Sectors where the defects existing made impossible implant perpendicular to occlusal plane 25º angled.
• Ball Attachment/wise lock/wise click systems- Located in all the areas of the mouth but usually used in the anterior area for overdentures.
• Healing Abutments / caps - Located in all the areas of the mouth.

Warning:
Care must be taken that restorative parts are not swallowed during the implantation procedure, thus rubber-dam application is recommended when applicable.
Care must be taken to apply the correct tightening torque to abutment retaining screw.

Precautions:
Proper case planning is essential to the long-term success of both the prosthesis and the implant. Overload is one of the key contributors to implant failure. One should ensure the implant size and abutment angulations are appropriate for the occlusal load. Splinting of off-axis loaded implants may be required to give better support.
Implant and abutment fractures can occur when applied loads exceed the designed normal functional tolerances. Potential overloading conditions may result from deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 25º, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing clenching), improper casting procedures, inadequate prosthesis fit, and physical trauma.
It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudates around the implant, pain, or any other unusual symptoms.
Store in a dry and clean place inside the original boxes when possible.

Adverse Effects:
The following complications may occur in consequence of implant placement: pain, discomfort, dehiscence, delayed healing, paresthesia, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, local and generalized allergic reaction, lack of integration, damage to adjacent teeth, loss of bone or teeth, and loss of implant. Other adverse effects may also occur as a result of iatrogenic factors and host responses. Additional information and steps to be taken can be found in the Surgical Manual.

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.

Single Use:
Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

Shelf Life:
No expiration date on abutments & prosthetic component.

Product Packaging:
Prosthetic components provided in sealed plastic bag/tube are also pre-cleaned for your convenience.

Cleaning and Sterilization:
Abutments are delivered in UNSTERILE condition. For sterilization, parts are placed in an appropriate autoclave. When sterilizing parts within a set, parts placed them in appropriate locations. The set is wrapped in sterilization wrap. To achieve a 10-6 Sterile-Assurance Level (SAL) autoclave time should be 15 minutes at 132ºC minimum. Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative. Exceeding these sterilization parameters may result in damage to plastic components. Verify the calibration of your unit to ensure recommended temperatures are not being exceeded. To ensure autoclave is performing effective, periodic use of biologic indicators should be considered. Chemclave sterilization is NOT recommended for any Surcam products.
All the plastic parts (not castable) should be sterilized by cold sterilization using Benzalcynhydrin solution.

Attachment of Angled Abutments

The attachment sequence is as follows:
1. Remove the angled abutment from the package.
2. Utilizing the abutment driver, deliver the abutment to the mouth and align it in the appropriate orientation.
3. Use 1.27mm 0.50 Hex driver to hand tighten (max. 25 N/cm2) the retaining screw. A contra-angle hand piece with a 1.27mm driver can also be used for initial delivery. The long driver is used if the delivery tool is attached to the abutment.
4. Verify with periapical radiograph that the abutment is seated completely into the implant and has engaged the internal hexagon.
5. A calibrated ratchet torque wrench can be used with the abutment driver.
6. In the conventional provisional restoration, to guide the healing of the soft and hard tissues around a dental implant, while simultaneously protecting the implant from plaque and debris it is recommended to place the titanium Healing Cap.

ZMaintenance and Periodic Care:
Patients are recommended to follow the indications provided by the dentist, to attend periodical controls and perform daily accurate hygiene.

Ball Attachment:
Titanium + Tin overdenture attachment is screwed on implants; the retention is achieved by the elastic cap which goes over the sphere's equator. Sphere's vertical dimension has been reduced for a smaller attachment. An expanding nylon elastic towel prevents the attachment unscrewing from the implant (available on request). A protective transparent disk is made of plastic and elastic material.

Instructions for Use - Ball Attachment:
Ball Attachment Titanium + Tin: Screw the attachment to the implant tightly with the standard hand driver or with the dynamometrical drill extension tool tightening up to 25 N/cm2.

MR conditional:
Non-clinical testing has demonstrated that Surcam 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 of 1.5 Tesla and 3.0 Tesla only.
Maximum spatial gradient magnetic field of 3000 Gauss/cm (30 T/m).
RF Excitation- Circularly Polarized
RF Transmit Coil Type - There are 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) of2 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.

Symbolic Information:

REF	Catalog Number
LOT	Batch Code
	Manufacturer
	Date of Manufacture
NON STERILE	Non sterile
2	Do not re-use, Single use
MR	MR conditional
	Keep away from sunlight
	Keep dry
2 STERILE	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
MD	Medical device
	Importer
	Information website for patients

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