Indications for Use:
The SURCAM Implants are intended for single or multiple replacements of lost teeth and provide a way to attach the prosthetic pieces in totally or partially edentulous patients. Operating surgeons/practitioners should be fully familiar with all indications, contraindications, recommendations, warnings and instructions, as well as all other product-specific information (technical product description, description of the surgical and restorative technique, catalogue sheet, etc.) of our system. They should be able to fully comply with these processes. Detailed instructions beyond those contained in these instructions for use concerning the possible combinations, product specific risks, preparatory steps, indications, contraindications, etc. These include of the surgical technique and descriptions of the product(s) as found in the appropriate catalogue sheet. SURCAM also recommends attending appropriate education, continuing education and user-training courses. The aforesaid mentioned documents and details of the training courses may be obtained from the complications, other negative effects or damages that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling thereof or unsuitable use or handling of the instruments, asepsis and so on. The operating surgeon is responsible for any such complications or other consequences. It is also the operating surgeon's responsibility to properly instruct and inform the patient on the functions, handling and necessary care of the product and on all known product risks.

Location in the mouth:
- Straight - Located in all the sectors (areas) of the mouth.
- Angled - Located in the anterior sector (areas) of the superiormaxillary (upper jaw) for 15° angled abutments. Sectors where the defects existing made impossible implant perpendicular to occlusal plane 25° 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.

Description:
The restorative abutments have a hex which engages the internal hex of the S-type, U-type and C-type implants. The abutments are available in multiple cuff heights in straight and offsets in 15°, 25°, 35° and 45° angulated configurations to provide correction for off-angle implant placement. The abutment is secured to the implant with an abutment retaining screw which is preassembled in the abutment. The abutment 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 abutment retaining screw are fabricated from titanium alloy.

Indications:
The straight and angled abutment are used for a terminal or intermediate abutment for screw-retained multiunit restorations. The 25° Angled Abutment must be used within 45° of parallelism for a splinted restoration. The 15° Angled Abutment must be used within 30° of parallelism for a splinted restoration.

Contraindications:
SURCAM prosthetics should not be used in patients who have contraindicated systemic or uncontrolled local diseases such as blood dyscrasias, diabetes, hyperthyroidism, oral infections or malignancies, renal disease, uncontrolled hypertension, liver problems, leukemia, severe vascular heart disease, hepatitis, immunosuppressive disorder, pregnancy, collagen and bone diseases. Relative contraindications may include habits such as tobacco use, alcohol consumption, poor oral hygiene, bruxism, nail biting, pencil biting and improper tongue habits depending on severity. SURCAM Multi-unit and Abutment for Screw prosthetics are contraindicated for single or multiple tooth replacements.

Warnings:
Surgical and restorative techniques required to place dental implants are highly specialized and complex procedures. Surgeons and all practitioners should be fully trained in such procedures and be competent in such implant practices. All practitioners should attend courses of study to familiarize themselves with implantology techniques. Improper technique can cause bone loss and implant failure. SURCAM Dental implant systems are intended to be used only with SURCAM Dental specially designed bone and prosthetics. Implants placed at severe angles relative to existing dentition or multiple implants placed at convergent/divergent manner can result in complex restorations that may overload implants. This overload may lead to the implant or it's prosthesis. A thorough diagnostic work-up and use of a surgical template is recommended to help ensure proper positioning of the implant or implants. Relative contraindications include the use of steroids, chemotherapeutic agents, bisphosphonates and anticoagulants. These and other medicines which may effect the surgical site, surrounding tissue, or patient's healing function can impact the success of the implant. Careful patient selection including consultation with the attending physician is strongly recommended prior to implant treatment for patients on any such medication. Placement of an implant adjacent to an infected tooth or a failing root canal treated tooth may cause the implant to fail. Excessive mobility, bone loss, or infection may indicate the implant is failing. Any implant which appears to be failing should be treated or removed as soon as possible. If removal is necessary, curette any soft tissue from the implant site. One may either allow site to heal as though it were an a traumatic extraction or perform guided tissue regenerative procedures as indicated. Due to the metal conductivity, electro surgery around the implants and intraoral abutment preparations without irrigation could result in tissue damage and implant failure. Patients should consult with their physician and imaging technician prior to undergoing an MRI procedure. The Straight and Angled Abutment have not been evaluated for safety and compatibility in the MR environment. The Straight Angled Abutment has not been tested for heating or migration in the MR environment.
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. Splanting of off-axis loaded implants may be required to give better support.

Breakage:
Implant and abutment fractures can occur when applied loads exceed the normal functional design tolerances of the implant components. 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 25 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing clenching), improper casting procedures, inadequate prosthesis fit, and physical trauma.

Changes In Performance:
It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional 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 that the patient has not been told to expect).

Treatment Planning:
Appropriate imaging techniques should be used to determine if adequate bone is available, and to determine the location of important anatomical landmarks, such as the mandibular canal, maxillary sinuses and adjacent teeth. Thorough clinical evaluation is imperative prior to all implant surgeries.

General Considerations:
Control of biomechanical stresses is the key factor to long-term success of the prosthesis. Even after implant integration, imbalances in occlusal forces can lead to implant failure. Implant patients should be monitored for signs of screw loosening, perimplant bone loss and tooth wear as signs of occlusal overloading.

Adverse Effects:
The following complications may occur relative to 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.

Sterility:
Abutments are delivered in UNSTERILE condition.

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:
Individual parts should be placed in appropriate autoclave or dry heat pouch prior to sterilization. When sterilizing parts within a set, parts should be placed in appropriate locations and set should be wrapped in sterilization wrap. The following sterilization parameters (method, time and temperature) are required to achieve a 10-6 sterile-assurance level (SAL). Autoclave time of 15 minutes for minimum of 132°C. Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table. 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 Dental products.

Technical Information:
Procedure for SURCAM Implants angled abutments. NOTE: During implant placement, it is recommended to orient the flat of the internal hex of the implant to be opposite the angle correction. The pre-attached multi-purpose fixture mount can be used to index the internal hex of the implant. The flat side on the wall of the fixture mount will line up with the flat side of the internal hex. NOTE: To put the abutment in the mouth use the abutment driver. The driver should be hand tightened (max. 25 Ncm) to the abutment to confirm adequate attachment of the tool to the abutment.

Use appropriate abutments and angulated components that correspond to the implant system being restored.

1. Remove the angled abutment from the abutment packaging.
2. Hand tighten the abutment.
3. Utilizing the abutment Driver, deliver the abutment to the mouth. Aligning the angled abutment in the appropriate orientation for desired angulation correction.
4. Use 1.27mm [0.50"] Hex Driver to hand tighten (max. 25 Ncm) the abutment retaining screw. A contra-angle hand piece with a 1.27mm driver can also be used for initial delivery. The long driver must be used if the abutment delivery tool is attached to the abutment.
5. Verify with periapical radiograph that the abutment is seated completely into the implant and has engaged the internal hexagon.
6. Tighten the abutment retaining screw to 25 Ncm with a calibrated torque wrench. The Torque Wrench can be used with the abutment driver for ratchet.
7. If the abutments will not be immediately restored with a provisional or final restoration, it is recommended to place the abutment titanium Healing Cap. To prevent irritation of the soft tissue and to prevent the ingress of material the screw access of the abutment cone.

Instructions for use - Ball-Attachment & Wiselock multi system
Refer to the IFU available on our website - Library/Instruction & Documents.

Device’s description and expected performances:
Retentive elastic attachments for the construction of dental prosthesis.

Precautions:
Choosing the right attachment is a dentist or dental technician responsibility according to the prosthetic project. Safety, Responsibility and Warranty: SURCAM attachments and components are manufactured in accordance to the Europeans norms on medical devices. No undesired collateral effects are expected or reported. Storage, transportation and cleaning process: Store in a dry and clean place inside the original boxes when possible.

WARNING:
Do not create any damages to the packaging while shipping. Product have no expiration date. The product is sold into a NON STERILE packaging, it’s recommended to proceed with sterilization process of the metal parts by following the standard
Maintenance and periodic care: Dentists have the responsibility to keep the proper functionality and retention of the devices (CAPS AND CLIPS) and assuring the safety of the patient by constant care. Guidelines for the patients: Patients are recommended to follow the indications provided by the dentist, to attend periodical controls and perform daily accurate hygiene. Set contain: Single implant attachment: 1 titanium attachment TiN (Ø 2,5), 4 assorted retentive caps, 1 protective disk.

Technical Specifications:
Ball Attachment on implants: Titanium + TiN single overdenture attachment to be screwed on implants, the retention is guaranteed by the elastic cap which goes over the sphere's equator. Sphere's vertical dimension has been reduced to obtain a smaller attachment.

Pre Fabricated Metal Houses Or Titanium:
The Internal Shape Is Designed To Contain The elastic retentive caps. The outside shape is designed to be inserted into resin mobile prosthesis or to be connected by using glue, composite cements or self polymerizing resin to metal parts, cast reinforcements or metal frames.

Unscrewing Systems:
Expanding nylon elastic towel designed to avoid the unscrewing of the attachment from the implant (available on request).

Protective Disk:
Mono-use disk, plastic and elastic material, transparent color.

Instructions For Use - Ball Attachment:
Ball Attachment Titanium + TiN: Screw the attachment to the implant with the standard driver, make sure the insertion of the metal tip is corrected. Screw tightly by hand until the process is completed. In alternative screw the attachment by using the proper dynamo-metrical drill extension tool tightening up to 25 N/cm2.

Application Of The Prosthesis In The Patient's Mouth:
Once the Ball Attachment are screwed into the implants, proceed with the insertion of the elastic protective disk over the equator of the attachment. Insert the retentive female cap inside the metal house by using the proper insertion tool, choose the female cap with the proper retention according to the case, than insert the metal house over the attachment with accurate pressure in order to have it snap over the equator. Test the resin mobile prosthesis in the patient mouth which will have the proper spaces corresponding to the attachments. Make sure the space is enough, if any interference should occur enlarge the space by using a bur until the interferences with the metal house are removed. Fill up the spaces with self polymerizing resin, insert the prosthesis inside the patient's mouth, verify the correct position, have the patient closing his mouth and wait until the resin is cured. Remove the prosthesis, refine and polish every exceeding material than deliver the prosthesis to the patient. In order to maintain the high quality standard offered by the Ball Attachment line we recommend the substitution of the retentive elastic components yearly. Any use of the Ball Attachment and components which does not follow the present instructions or the others SURCAM literature is considered improper.