ACE SURGICAL SUPPLY CO., INC.

infinity

infinity TRI-CAM DENTAL IMPLANT SYSTEM

INSTRUCTIONS FOR USE

PHASE I: IMPLANT PLACEMENT

PRODUCT DESCRIPTION
The infinity TRI-CAM Dental Implant System is designed for use in totally edentulous mandibles or maxillae or as a terminal or intermediary abutment for fixed or removable bridgework. The system can also be used for single tooth restorations. The TRI-CAM Dental Implant System uses a two-stage implantation process and is not intended for immediate loading.

INDICATIONS
The TRI-CAM Dental Implant System is used in indications for oral endosseous implants in the maxilla and/or mandible as part of a functional and aesthetic oral rehabilitation in partial or fully edentulous patients.

The TRI-CAM Dental Implant System is designed for use in totally edentulous mandibles or maxillae or as a terminal or intermediary abutment for fixed or removable bridgework. The system is intended for use with all standard straight abutment prosthetics and is not intended for use with angled abutments. The system can also be used for single tooth restorations. The TRI-CAM Dental Implant System uses a two-stage implantation process and is not intended for immediate loading.

The TRI-CAM Dental Implant System is compatible with 0 (zero) degree, straight version of the Atlantis™ Abutment for Nobel Replace Interface.

GENERAL CONTRAINDICATIONS
The TRI-CAM Dental Implant System is contraindicated for patients that have current, latent or active infections, uncontrolled diabetes, chronic high dose steroid therapy, clotting disorders, current anticoagulant therapy, metabolic bone disease or other systematic disorders which affect bone or wound healing. Further contraindications include using the product in areas of poor or limited vascular supply, areas of insufficient quality or quantity of bone, areas with receding gingival disease, in patients with titanium sensitivity, or severe psychological disorder, xerostormia, intra oral infection or malignancies, and in patients with uncontrolled para-functional habits. Patients undergoing such treatments that expose the dental implant to radiation, chemotherapy, or any magnetic imaging procedures should consult their active physician before undergoing dental implant surgery.

PRECAUTIONS
It is important to obtain a thorough medical history from the patient to determine if conditions exist that will make implant placement difficult or contraindicated because of anatomical conditions, surgical or general risk, impaired healing capacity and/or osseointegration. Furthermore, patients with inadequate compliance, inadequate oral hygiene, periodontis, bruxism or oral mucosal changes must be thoroughly evaluated before any implants can be placed.

ACE Surgical Supply Company, Inc., or its affiliates cannot be held responsible for any complications, or failures that may result from incorrect or off-label use of this product. The operating surgeon assumes responsibility for any negative outcome as a result of this product being used off-label or deviating from these instructions for use. It is the responsibility of the surgeon to properly educate the patient on all aspects of this product, its risks, and its required maintenance.

WARNING
Surgical techniques required to place dental implants are highly specialized and complex procedures. Practitioners should attend courses of study to prepare them in established techniques of oral implantology. Improper technique can cause implant failure. The TRI-CAM Dental Implant System is designed to be used by a dental practitioner with this appropriate implant training. The use of this system or any of the ACE Surgical dental implant products requires that the user be thoroughly familiar with the product and the methods for its use and application. The user must also be familiar with all of the instruments and the surgical procedures that are required. Reasonable judgment in deciding when and where to use the product must be determined before any surgical procedures can commence.

Improper use of this product can result in implant failure and/or loss of supportive or surrounding bone. Insufficient implant stability, excessive bone loss, or localized infection may indicate that the implant is failing. Implants that appear to be failing should be immediately treated or removed. Conditions such as excessive loading, caused by bruxism, clinching, or a cross bite may lead to these implant failures, and as such should be diagnosed and treated prior to implant surgery.

POTENTIAL SIDE EFFECTS
Some of the potential side effects include; chronic pain, swelling, infection, poor surgical site healing, surrounding tissue sensitivity, allergic reactions, hemorrhaging, exfoliation, localized or systemic infections, uncontrolled bone loss, nerve damage and temporary or long term tissue paresthesia. Unsuccessful osseointegration will be evidenced by infection, mobility or bone loss. Any failed implant should be removed as soon as possible and all granular tissue removed from the implant site.

PATIENT SELECTION
Patient motivation is a key factor in achieving success with any implant. The patient must be willing to practice the oral hygiene necessary for implant maintenance.

Patient evaluation prior to implant surgery is extremely important, including determination of general health, oral hygiene habits and status, motivation toward good dental care, and anatomic acceptability. Thorough evaluation of the patient's medical status and health history is mandatory. Panoramic and periapical radiographs as well as thorough oral inspection and palpation are recommended to determine anatomic landmarks, dental pathology and adequacy of bone.

A cephalogram is suggested for totally edentulous patients. Any oral condition that adversely affects natural teeth, if uncorrected, will have an adverse effect on the implant. Periodontal disease, abnormal bone conditions, severe bruxism, and cross-bite situations must be evaluated and corrected or use of the implant may be contraindicated.

PREOPERATIVE TREATMENT PLANNING
Selection of proper implant size is crucial to the long-term success of the implant. During preoperative planning the surgeon must have exact knowledge of the measurement system employed and maintain an appropriate safety margin from teeth and vital structures. Permanent damage to nerves and/or vital structures can be caused if drilling depths are not correctly determined relative to the radiograph and extends beyond the planned depth. In addition, implant site and occlusion must be acceptable. It is desirable to utilize the maximum implant length and diameter possible for greatest stability of the overlying prosthesis. Radiographs must be accurately measured to allow for proper implant length selection to avoid the maxillary sinus space, the floor of the nose, the mandibular canal, or perforation of the inferior aspect of the mandible. Measurements can be made directly on panographic films using a millimeter ruler. Corrections should be made for the degree of enlargement produced by the particular radiographic equipment. At least 2mm of bone must remain below the implant when inserted (e.g., 10mm of bone is required to insert an 8mm length implant body). Ridge contour should be adequately palpated to estimate an angle of insertion which will achieve parallelism with other implants and natural tooth abutments where indicated. Adequacy of space between the alveolar ridge crest and opposing natural or prosthetic dentition also must be determined.

Prior to implant surgery, the final prosthesis for the patient should be designed.

Radiographs, study casts, and clinical evaluation should be used to determine the position and angulation of all implants. In some instances, a surgical stint may be desirable.

SURGICAL PROCEDURES
As in any surgery, it is important that the implantation procedure be aseptic. The TRI-CAM dental implant bodies are provided as a single implant in a GAMMA radiated sterile plastic vial.

The surgical procedure can be performed in the office under local anesthesia with or without intravenous sedation or in a hospital surrounding if the doctor or the patient prefers.

HANDLING AND STERILIZATION
The TRI-CAM dental implant bodies are provided as a single implant in a GAMMA radiated sterile plastic vial. Clinically contaminated implants cannot be re-sterilized.

Only Sterile titanium instruments should be used to handle the implant.

Sterilization: All non-sterile ACE surgical instruments must be sterilized prior to use. ACE instruments must be removed from individual plastic wrapping before sterilizing. All instruments should be sterilized by autoclave or dry heat following the standard sterilization protocol.

Standard Sterilization Parameters:
- **Autoclave**.....250°F.....120°C.....15 minutes.....15 PSI (min.)
- **Dry Heat**.....340°F.....170°C.....2 hours

* A standard autoclave bag should be used. Check trays, autoclave interior, and water supply for cleanliness. The autoclave should have a drying cycle.

SITE PREPARATION
Make a mesio-distal incision along the buccal side of the alveolar crest through the mucoperiosteum and attached gingiva to the bone. The incision should be long enough to permit adequate reflection without tearing the tissue and also to provide a broad field of view. Using a periosteal elevator, carefully lift the periosteum to expose the alveolar bone only as necessary to provide an adequate surgical working area. Retractors or sutures should be placed to hold the tissues. Spinous ridges or other bone irregularities should be removed using a rosette bur or a rongeurs forceps. Removal of bone, however, should be kept to a minimum to maintain the blood supply to cortical bone. (Insufficient bone width, abnormal defects or contours not previously detected may now contraindicate placement of the implant.) At least a 4-6 mm (edge to edge) should be maintained between implants and/or adjacent natural dentition. In addition, a minimum of 1mm must be maintained between cortical plates.

GENERAL INSTRUCTION FOR IMPLANT BED PREPARATION
It is mandatory that all bone cutting procedures be performed with a low speed (800-1200 rpm), high-torque, internally-irrigated handpiece. Profuse irrigation with sterile water or sterile saline is required. Use of this type of handpiece will minimize excessive heat generation and preserve the vitality of bone which is in contact with the implant. Any thermal trauma during this procedure can severely affect the quality of implant osseointegration, so extreme care must be taken. Furthermore, before drilling, confirm proper implant body size selection and location.

All drilling must be done with a straight, up-and-down pistoning motion in order to avoid the creation of an oval-shaped site.

Since the pilot hole establishes the ultimate location and angle of the implant, it should be prepared with the complete prosthodontic treatment plan in mind. Questions as to proper angularity and draw with respect to the ridge, existing dentition, or additional implants should be resolved prior to the creation of each implant pilot hole.

To assist in the drilling process and to create an optimal osteotomy, clean the drill cutting edges often to remove any tissue debris and insure a sharp cutting surface.

STEP BY STEP PREPARATION OF THE IMPLANT BED
Implant bed preparation should be performed in a clear field so that the operator can view the actual site at all times to properly prepare and fit the implant.

1. Keeping in mind, the importance of the pilot hole (see General Instruction for Implant Bed Preparation) the pilot drill is used to create a well-defined osteotomy.
2. To establish parallelism and draw between and among implants, prepare the first pilot hole. Flush the pilot hole to remove bone debris. Insert one parallel pin using the end which corresponds in size to the pilot drill. Leave the parallel pin in the first hole and move on to the next preparation while referring to angularity and draw requirements established by the first implant bed preparation. Proceed until all pilot holes are drilled, leaving a parallel pin in each site as it is completed. Check parallel pins for proper angularity before proceeding with the respective implant sizes intermediate and final drilling sequences.
3. Use the appropriate drilling sequence of intermediate and final drills which correspond to the defined diameter and length on the TRI-CAM dental implant body chosen to create the desired osteotomy. Minor correction to obtain proper parallelism can be made at intermediate drilling stage. Check for proper parallelism using the opposite end of the parallel pin which corresponds to the diameter of the first intermediate drill.
4. Once the defined implant size osteotomy is created, thoroughly clean the site with additional sterile water or sterile saline prior to implant placement.

IMPLANT PLACEMENT:
1. Open the outside packaging box of the TRI-CAM Dental Implant and locate the data record labels inside the box. Place the appropriate labels on the patient's medical chart to record the implants lot number and product description.
2. Remove the TRI-CAM Dental Implant Tyvek® sealed blister package from the outside box. Open this blister package over a sterile field by locating and pulling off the sealed Tyvek® lid. With the blister package open, drop the sterile inner implant vial and dental implant onto the sterile field.
3. Visually locate the upper side of the implant vial that contains the implant. This upper side is covered with a labeled tamper proof tape. Once located, open this sterile implant vial by breaking the tamper proof tape and removing the cap using a gentle twisting and pulling motion.
4. Once this cap is removed, while keeping this vial opened in a vertical direction, access and pick up the TRI-CAM Dental Implant body from the vial by using either a hand or contra-angle implant driver tool. When using these driver tools, care must be taken to carefully rotate and engage the mating cams of the implant and holding mechanism of the tool in a downward direction, before it can be taken out of the vial and delivered to the prepared osteotomy.
5. With the TRI-CAM Dental Implant attached to the driver tool, insert the implant into the prepared osteotomy using an implant placement speed of (20rpm) and a maximum insertion torque of 50 N-cm. External irrigation may be used to minimize heating during this process.
6. Continue inserting the dental implant body into the osteotomy until all the threads of the implant are completely seated into the surgical bony site and the upper neck of the implant fixture sits flush with the surrounding bony ridge.
7. After placement, disengage the hand or contra-angle implant driver tool from the impant by pulling off the tool in a straight upward direction.

COVER SCREW PLACEMENT – PHASE I IMPLANT HEALING:
1. After the implant is correctly placed, cover the implant body's internally threaded features with a Phase I cover screw. Returning back to sterile field visually locate the bottom side of the implant vial that contains the Phase I cover screw. Once located, remove the cap using a gentle twisting and pulling motion to expose the screw.
2. Using a 1.25 mm spline driver tool, unthread the Phase I cover screw from the plastic cap by unthreading it in a counterclockwise direction.
3. With the Phase I cover screw attached to the 1.25 mm spline driver tool, deliver and thread the cover screw into the top of the implant body in a clockwise direction. Use care during the delivery process to prevent the screw from coming off of the driver and falling into a non-sterile area or the patient's mouth.

4. Completely seat the Phase I cover screw into the implant and secure it into place with the proper seating torque using a 10 N-cm torque limiting wrench.

5. Once the screw is properly attached to the implant, close over the implant and surgical site using a tension-free suturing procedure.

POSTOPERATIVE COURSE
The patient should be instructed to follow a routine postsurgery regimen, including cold packs for the initial 24 hours. An antibiotic of choice may be prescribed. The sutures may be removed after 1 week. It is suggested that any removable prosthesis resting on the implant be adequately relieved and relined using a soft tissue conditioner reline material.

A healing period of approximately 4-6 months is recommended. It is important that the implants be left unloaded during the healing period.

The patient should be seen periodically until the prosthesis is seated to monitor proper healing of the soft and hard tissues. During these appointments attention should be given to the tightness of sutures and incipient of any infections.

Insufficient availability of bone, poor bone quality, poor patient oral hygiene, and generalized diseases (diabetes, etc.) may contribute to lack of osseointegration and subsequent implant failure and are contraindications.

PHASE II PROSTHODONTIC TREATMENT

DESCRIPTION
The ACE Implant System is designed for use in the totally edentulous mandibles or maxillae or as a terminal or intermediary abutment for fixed or removable bridgework. The system can also be used for single tooth restorations.

PREOPERATIVE PLANNING
Prior to implant surgery, a careful treatment plan should be developed involving the patient, surgeon and prosthodontist or restorative dentist. The final prosthesis is chosen based upon patient anatomy, oral hygiene habits, functional requirements and patient preference. Panoramic and periapical radiographs, study casts and clinical evaluations are used to determine proper prosthetic treatment. The placement and position of the implant bodies is determined during this pretreatment planning.

SURGICAL PROCEDURE FOR EXPOSURE OF THE IMPLANT
As a general guideline, a healing period of approximately four to six months is allowed. Following this stage, the implant phase I cover screw is uncovered. Location can be determined by palpation of the soft tissue or use of a periodontal probe. To surgically expose the cover screw, a scalpel, tissue punch or electrosurge is used. The cover screw is removed with a 1.25mm spline driver tool. Thoroughly remove all bone and soft tissue from the superior aspect of the implant body using an appropriate instrument. The presence of tissue or bone fragments between the implant and abutment can lead to abutment loosening. Do not use a bur or drilling instruments which may compromise the integrity of the implant.

FINAL RESTORATIONS
Proper restoration is essential for the success of any implant. The TRI-CAM Dental Implant is designed for use with either fixed or removable prosthetics. Choice of the final prosthesis is, as determined prior to implant surgery, will dictate the abutment or attachment selected. The TRI-CAM Dental Implant System is compatible with 0 (zero) degree, straight version of the Atlantis™ Abutment for Nobel Replace Interface.

POST INSERTION CARE
Once the prosthesis has been seated, occlusion is verified. Lateral forces to the implant must be minimized as well as all possibilities of traumatic occlusal loading. Whenever excessive forces are applied to an implant and/or prosthetic restoration, for whatever reason, the potential for an implant and/or prosthetic restoration fracture and failure is uncontrollable. If any sign of these conditions begin to be realized by either the patient or physician, immediate attention to fix the failing situation must occur. To maximize and assist the structural success of the implants and its fabricated prosthetic restoration, the following recommendations are suggested:

1. Do not splint implants with natural teeth to create a final restoration.
2. Whenever possible maximize the number of implants used to appropriately fit in the surrounding bone anatomy.
3. Whenever possible maximize the size of the implant length and diameter to appropriately fit in the surrounding bone anatomy.
4. Minimize any cantilevers prosthetic restoration.
5. When replacing a long area of dentition, consider multiple splinted implant to support the final restoration.

In addition, proper tooth contour is created to ensure adequate embrasure for proper oral hygiene. The patient is instructed on correct oral hygiene procedures especially around the gingival margin of the implant. Recall is recommended every four months.

HOW SUPPLIED
The TRI-CAM Dental Implant is available in a single sterile plastic vial.
The following sizes are available:

TYPE	DIAMETER	LENGTHS
Screw Type	3.5 mm	8, 10, 11.5, 13, 16 mm
Screw Type	4.3 mm	8, 10, 11.5, 13, 16 mm
Screw Type	5.0 mm	8, 10, 11.5, 13, 16 mm

SHELF LIFE
The TRI-CAM Dental Implant is provided sterile using a defined GAMMA radiation process. As sold, these products have the appropriate labeling indicator that shows the month and year, with the hourglass symbol, to define the expiration to this package. If the outer Tyvek® package is compromised in any way, do not use this product as the sterile barrier may be breached.

CAUTION
Federal (USA) law restricts this device to sale by or on the order of a licensed dentist or physician, and use by any other person is prohibited,

FOR TECHNICAL ASSISTANCE AND MORE INFORMATION OR TO ORDER PLEASE CALL OUR TOLL FREE NUMBER, 800.441.3100.

Labeling Symbols

Symbols may be used on some international package labeling for easy identification.


Symbol for "Use-by date"


Symbol for "Do not re-use"

Symbol for "Do not resterilize"


Symbol for "Do not use if the product sterilization barrier or it's packaging is compromised"


Symbol for "Caution (see instructions for use)"

STERILE R Symbol for "Sterilized using irradiation"

LOT Symbol for "Batch code"

CE 0120 Product complies with requirements of directive 93/42/EEC for medical devices


Symbol for "Manufacturer"

℞ only Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist.

EC REP Symbol for "Authorized representative in the European community"

REF Symbol for "Catalogue Number"


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