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. Through evaluation of the patient's medical status and 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.

An orthopantomogram 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 cleft-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 deficiencies 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 panoramic films using a millimeter ruler. Connections 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 implant length body). Ridge contour should be adequately palpiated to estimate an angle of implant placement 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 prostheses 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 stent may be desirable.

SURGICAL PROCEDURES
As in 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 setting 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. Clinical care must be unsterile.

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 tray, 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 incisions should be long enough to permit adequate reflection without tearing the tissue and also to provide a broad field of view. Using a punctured elevator, carefully lift the periosteum to expose the alveolar bone only as necessary to provide an adequate surgical working area. Retractors or suture should be placed to hold the tissue. Spontaneous ridges or other bone irregularities should be removed using a rotary bur or a rongeur 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 cannot be corrected 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-watered handpiece. Provocative irrigation with sterile water or sterile saline is required. Use of this type of handpiece will maximize 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, i.e., 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 prosthetic treatment plan in mind. Questions as to proper angulation and drill with respect to the existing dentition, or additional implants should be realized prior to the creation of each implant pilot hole.

To assist in the drilling process and to create an optimal aesthetics, clean the drill cutting edges often to remove any tissue debris and ensure 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 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 angulation and drill 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.

3. Check parallel pins for proper angulation before proceeding with the respective implant sizes intermediate and final drilling sequences.

4. Use the appropriate drilling sequence of intermediate and final drills which corresponded to the defined diameter and length on the TRI-CAM dental implant body chosen together with the designed osteotomy. Minor corrections in connection 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.

5. 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 STERILE labeled inside 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 tearing 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 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 open 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 cores 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 rotation 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 bone site and the upper neck of the implant future site flush with the surrounding bone.

7. After placement, disengage the hand or contra-angle implant driver tool from the implant by pulling off the tool in a straight upward direction.

COVER SCREW PLACEMENT – PHASE I 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, tightly 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, unscrew the Phase I cover screw from the plastic cap by unwinding 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 screw cover 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.
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 prostheses 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 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 disease (diabetes, etc.) may contribute to lack of osseointegration and subsequent implant failure and are contraindications.

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 Interframe.

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 unmitigable. 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.
5. When replacing a long area of dentition, consider multiple splinted prosthetic restoration, the following recommendations are suggested:

SHELF LIFE
The TRI-CAM Dental Implant is provided sterile using a defined GAMMA radiation process.