INSTRUCTIONS FOR USE

Important Information – Please Read Prior to Use

English

CTL Medical Corporation (d/b/a: CTL Amedica)
2052 McKenzie Drive, Building 1, Carrollton, TX 75006
Phone: 214.545.5820 | Fax: 888.831.4892
www.ctlamedica.com

DEVICE SYSTEM NAME

VAN GOGH™ Anterior Cervical Plate System

PURPOSE

The VAN GOGH™ Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7).

DESCRIPTION

The VAN GOGH™ Anterior Cervical Plate System implants consist of plates and plate screws. All components are manufactured from titanium alloy (Ti-6Al-4V) per ASTM F136. The plates are available in lengths ranging from 12-104mm (measured hole to hole) to accommodate one to four levels of fixation. The system also includes 4.0mm and 4.5mm titanium alloy screws which are available in lengths ranging from 10mm-20mm. Screws are available in variable and fixed angle options, as well as self-drilling and self-tapping options.

INDICATIONS

The VAN GOGH™ Anterior Cervical Plate System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with:

1. degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. spondylolisthesis
3. trauma (i.e., fractures or dislocations)
4. tumors
5. deformity (defined as kyphosis, lordosis, or scoliosis)
6. pseudarthrosis
7. failed previous fusion
8. spinal stenosis

CONTRAINDICATIONS

1. Active systemic infection or an infection localized to the site of the proposed implantation
2. Severe osteoporosis may prevent adequate fixation of screws and thus preclude the use of this or any other spinal instrumentation system
3. Patients who have been shown to be safely and predictably treated without internal fixation
4. Open wounds

RELATIVE CONTRAINDICATIONS

Relative contraindications include any entity or condition that totally precludes the possibility of fusion (e.g., cancer, kidney dialysis or osteopenia), obesity, certain degenerative diseases, and foreign body sensitivity.

POTENTIAL ADVERSE EVENTS

1. Nonunion, delayed union
2. Bending or fracture of implant
3. Loosening of the implant
4. Metal sensitivity, or allergic reaction to a foreign body
5. Infection, early or late
6. Decrease in bone density due to stress shielding
7. Pain, discomfort, or abnormal sensations due to the presence of the device
8. Nerve damage due to surgical trauma or presence of the device
9. Neurological difficulties including radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia
10. Vascular damage could result in catastrophic or fatal bleeding
11. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period
12. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis
13. Bursitis
14. Paralysis
15. Esophageal perforation, erosion or irritation
16. Screw back-out, possibly leading to esophageal erosion, implant loosening, and/or reoperation for device removal
17. Damage to lymphatic vessels and/or lymphatic fluid exudation
18. Spinal cord impingement or damage
19. Fracture of bony structures
20. Degenerative changes or instability in segments adjacent to fused vertebral levels
21. Death

WARNINGS

MRI Safety Information:
The VAN GOGH™ Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. The VAN GOGH™ Anterior Cervical Plate System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the VAN GOGH™ Anterior Cervical Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

The following are specific warnings, precautions and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient before surgery.

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, fracture of the vertebra, neurological injury, and vascular or visceral injury.

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT
The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.
Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. MIXING METALS CAN CAUSE CORROSION.
There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerates the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.

4. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be extremely important to the eventual success of the procedure:

   a. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
   b. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
   c. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
   d. Foreign body sensitivity. The surgeon is advised that no pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
   e. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful

WARNING: If bony fusion does not occur within an expected period of time, the screws may break due to the high and sustained loading of these devices. This has been noted in patients with delayed, pseudoarthrosis or non-union and can result in the need to revise the device(s).

PRECAUTIONS

Based on the fatigue testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the anterior cervical plate system. The implantation of the anterior cervical plate system should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

1. SURGICAL IMPLANTS MUST NEVER BE REUSED.
An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. 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, illness or death. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents.

2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.
Contouring of metal implants should be done only with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage of the implant. Do not use implant if damage is suspected. Excessive torque applied to the screws when seating the plate may cause failure of the bone resulting in stripped threads and/or compromised screw purchase.

3. BENDING THE CONSTRUCT.
Titanium alloy components should never be bent sharply or reverse bent. If a construct is over-contoured it is recommended

that a new construct is contoured correctly rather than reverse bending the over-contoured construct.

4. REMOVAL OF THE IMPLANT AFTER HEALING.
If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture or deformity. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved in a second surgery.

5. ADEQUATELY INSTRUCT THE PATIENT.
Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and participating in any type of sports. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

CHOICE OF IMPLANTS
The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. Further information on the use of this system will be made available on request.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.
6. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. Unless sterile packaged, all parts should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE
1. The instructions in any available applicable surgical technique manual should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. To assure proper fusion below and around the location of the instrumentation, autograft should be used. Autograft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
5. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

POSTOPERATIVE
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the device are complications which can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions, and any type of sport participation. The patient should be advised not to smoke or consume excess alcohol during the bone healing process.
3. The patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device. It is important that immobilization of the union is established and confirmed by roentgenographic examination. Where there is a non-union, or if the components loosen, bend, and/or break, the device should be revised and/or removed immediately before serious injury occurs. Until maturation of the fusion is confirmed by radiographic examination, external immobilization (such as bracing) may be recommended, based on physician judgment. Instructions to the patient to

reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING

Components should only be accepted if received with the factory packaging and labeling intact. All sets should be carefully inspected before use. In particular, check for completeness of the set and integrity of the components and/or instruments. Any damaged packaging and/or product must be returned to CTL Medical Corporation.

EXAMINATION

Instruments must always be examined by the user prior to use in surgery. Examination should be thorough, and in particular, should take into account a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of location holes or cannulations, and the presence of any cracks, bending, bruising or distortion, and that all components of the instrument are complete. Never use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise unfunctional.

STORAGE & HANDLING

CTL Medical Corporation VAN GOGH™ Anterior Cervical Plate System should be stored in a dry environment, protected from direct sunlight and at an ambient temperature in their original packaging.

CLEANING & STERILIZATION

Implants are supplied non-sterile and are for single use only. So, all implants used in surgery must be sterilized by the hospital prior to use. Otherwise, Instruments are supplied non-sterile and may be re-used. Instruments must be thoroughly cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization. Unless just removed from an unopened CTL Medical Corporation package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to CTL Medical.

Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Disassemble instruments with removable parts. Methods of cleaning VAN GOGH™ re-usable instruments are provided in these instructions, a manual method and a method using an automated washer disinfector. Whenever possible the automated method should be used. The automated cleaning process is more reproducible and, therefore, more reliable, and staff are less exposed to the contaminated devices and the cleaning agents used. Whichever method is used, staff should use suitable protective clothing and equipment at all times. In particular, take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product. The guidance provided by the detergent manufacturer concerning concentrations and temperatures shall be observed. If these concentrations and temperatures are exceeded significantly, discoloration or corrosion could occur with some materials. This could also happen if rinsing after cleaning and/or disinfecting is insufficient. CTL Medical Corporation does not recommend any specific cleaning and/or disinfection agent. For cleaning or disinfecting reusable instruments, only specifically formulated cleaning agents and/or disinfectants should be used. Do not alter the concentrations specified by the detergent manufacturer. The quality of the water used for diluting cleaning agents and/or disinfectants and for rinsing re-usable instruments should be carefully considered. Application of freshly prepared purified water/highly purified water or sterile water for rinsing purposes with less than 100 cfu/ml and Mineral residues from hard water, as well as higher contamination with microorganisms and endotoxins, can result in staining of the device or prevent effective cleaning and decontamination.

Cleaning Instruction: Point of Use

- Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe.
- Place devices in a tray of distilled water or cover with damp towels.
- Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
- Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

Preparation Before Cleaning

- Symbols or specific instructions etched on instruments or instrument trays and cases should be strictly followed.
- Where applicable, multi-component instruments should be disassembled for appropriate cleaning.
- Disassembly, where necessary is generally self-evident. Care should be exercised to avoid losing small screws and components.
- All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer.
- Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.
- Enzyme solutions should be changed on a regular basis in order to ensure effectiveness.

Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

Cleaning & Disinfection Options

1. Manual - Enzymatic soak and scrub followed by sonication.
2. Automated - Enzymatic soak and scrub followed by an automated washer/disinfector cycle.

Note: If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis.

Manual Cleaning Steps

1. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. Scrub using a soft-bristled, nylon brush until all visible soil has been removed.
2. Remove the device from the enzyme solution and rinse in purified water for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
3. Place prepared cleaning agents in a sonication unit.
4. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50kHz.
5. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/ or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
3. Repeat the sonication and rinse steps above.
4. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

Automated Cleaning Steps

Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure below. An automated system may be used as a follow-up method.

1. Completely submerge the instruments in enzyme solution and allow to soak for 10 minutes. Use a soft nylon-bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors, and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon- bristled brush.
2. Remove devices from the enzyme solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
3. Place instruments in a suitable washer/disinfector basket and process through a standard washer/disinfector instrument
    a. Rinse 3 times using purified water for 30 seconds after wash using the enzymatic detergent in the ultrasound cleaner at 35-45ºC for 3 minutes.
    b. Perform the ultrasound rinsing repeatedly subjected 3 times for 3 minutes using the purified water at 35-45ºC.
    c. Dry at 100ºC (±5ºC) for 30 minutes.

Note: Use of a sonicator at 45-50kHz will aid in thorough cleaning of devices.

Note: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

CAUTION:

- All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field.
- Use of sodium hydroxide (NaOH) is prohibited.
- Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
- Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed.
- Verify that the instruments are in visually clean.

Inspection

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your CTL Medical representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your CTL Medical Corporation representative for a replacement.

Sterilization

All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field.

Sterilization: recommended method to achieve a degree of sterility equal to at least 10-6. The gravity displacement sterilization parameters we suggested comply with AAMI ST79. CTL Medical recommends the following parameters:

METHOD	Steam	Steam
Cycle	Gravity	Pre-Vacuum
Temperature	132°C (270°F)	132°C (270°F)
Exposure	15 minutes	4 minutes
Dry Time	45 minutes*	45 minutes*

*(15 Min Open Door Time + 30 Min Cool-Down Time)

It is important to note that an FDA-cleared sterilization wrap, package or sterilization container system should be used to enclose the case or tray in order to maintain sterility.

Although the treatment of the instrument, materials used, and details of sterilization have an important effect, for all practical purposes, there is no limit to the number of times instruments can be resterilized.

SINGLE USE/LIMITS ON PROCESSING

Products intended for single use must not be reused. Single use instruments are identified with marking “SINGLE USE” or with the associated symbol on the device and/or packaging. 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, illness or death. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents. Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on CTL Medical Corporation implants and instruments.

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or CTL Medical Corporation. Further, if any of the implanted spinal system component(s) ever malfunctions, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any CTL Medical Corporation product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

DISPOSAL INSTRUCTIONS

If product return is not possible then the affected product shall be maintained and/or disposed of according to the policy of the user facility.

LIMITED WARRANTY

CTL Medical Corporation products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact CTL Medical Corporation for current information.

FURTHER INFORMATION

Recommended directions for use of this system are available at no charge upon request. If further information is needed or required, please contact CTL Medical Corporation .

SYMBOL TRANSLATION