CTL MEDICAL

DEGAS™

ANTERIOR CERVICAL PLATE SYSTEM

Purpose

The Degas Anterior Cervical plate system components are temporary implants that are intended for anterior interbody screw/plate fi ation of the cervical spine during the development of a cervical spinal fusion.

Description

Degas Anterior Cervical plate system consists of a variety of shapes and sizes of Main Plates, screw, sub-plate, rivets and the associated instruments. The sub-plate is pre-assembled to the main plate and designed to prevent screws from backing out using the elastic beh vior during the screw insertion. The ri ets are also pre-assembled to the main plate and designed to assemble the sub-plate to the main plate firml . Each component is subjected to a color anodizing process to differentiate the screw type and diameter and to make the surgical process easy. The plates range in length to accommodate one, two, three, and four level procedures. Main plate are available from 20mm to 110mm. Screws are available in lengths from 10mm to 20mm in 2mm increments. The screws have either a 3.5mm or 4.0mm diameter. They are fixed self-tapping, Variable self-tapping screw, fixed self-drilling screw, Variable self-drilling and are available in lengths ranging from 10mm to 20mm in 2mm increments. The Degas Anterior Cervical plate system components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6AI-4V ELI) that conforms to ASTM F 136.

The Degas Anterior Cervical plate system consists of main plate, screw, sub-plate, rivet.

1) Main plate : has window in the middle of plate. Designed to assemble with Sub-plate, rivet.
2) Sub-plate : is pre-assembled to the main plate.
3) Rivet : the rivet makes the sub-plate fixed firmly.
4) Screw : To fix the bone segments, the screw is inserted to the bony structure though the plate. There are 4 type of screw in the system. For the motion, variable type and fixed type are available. For the shape, self-tapping screw and self-drilling screw are available. Intended Use / Indications for Use The Degas Anterior Cervical plate system is intended for anterior fixation to the cervical spine. The specific clinical indications include: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

WARNING: The device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Note : The Degas Anterior Cervical plate system has not been evaluated for safety and compatibility in the MR environment. The Degas Anterior Cervical plate system has not been tested for heating or migration in the MR environment.

Contraindications

Contraindications include, but are not limited to:

1. Infection, lo al to the operati e site.
2. Signs of local inflamm tion
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Any medical or surgical condition which ould preclude the potential ben fit of spinal impla t surgery, such as the elevation of se - imentation ate unexplained by other diseases, elevation of whi e blood count (WBC), or a marked left shift in the WBC d erential ount.
8. Rapid joint disease, bone absorption, o teopenia, and/or osteoporosis. Osteoporosis is a relati e contraindication since this condition m y limit the degree of obtainable correction, the amou t of mechanical fi ation, and or the quality of the bone graft
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion or whe e fracture healing is not required.
11. Any case requiring the mixing of metals from di erent components
12. Any patie t having inadequate tissue overage over the operati e site or where there is inadequate bone stock, bone quality or anatomical definitio
13. Any case not described in the indications
14. Any patie t unwilling to cooperate with the post-operati e instructions
15. Any time impla t utili ation ould interfere with anatomical structures or expected physiological performance.

Potential Ad erse Events

All of the possible adverse events associated with spinal fusion surgery without instrumentation a e possible.

With instrumentation, a li ting of possible ad erse events includes, but is not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) react to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears.
8. Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
9. Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
10. Loss of bowel and/or bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
13. Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Cessation of any potential growth of the operated portion of the spine.
16. Loss of spinal mobility or function.
17. Inability to perform the activities of daily living.
18. Bone loss or decrease in bone density, possibly caused by stress shielding.
19. Graft donor site complications including pain, fracture, or wound healing problems.
20. Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
21. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
22. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
23. Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
24. Change in mental status.
25. Death.

Note: Additional surgery may be necessary to correct some of these-anticipated adverse events.

WARNINGS and PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. The Degas Anterior Cervical plate system is only a temporary implant used for the correction and stabilization of the spine. This system is also intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the Degas Anterior Cervical plate system is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction and proper selection and placement of the implant are important considerations in the successful utilization of the Degas Anterior Cervical plate system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.

CAUTION: For use on or by the order of a physician only.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Other preoperative, intraoperative, and postoperative warnings are as follows:

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 otherwise damaged. If the green colored and “C” shaped Sub-plate in the plate is shrunk, do not use the plate. Implants and instruments should be protected during storage especially from corrosive environments.
4. 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.
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. The Degas Anteri-or Cervical plate system components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative

1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
3. When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary.
4. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
5. Bone grafts must be placed in the area to be fused and the gra must be extended from the upper to the lower vertebrae to be fused.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat gener-ated from the curing process may also cause neurologic damage and bone necrosis.
7. Before closing the soft tissues, all of the screws should be seated onto the plate. Recheck the tightness of all screws after finishing to make sure that none has loosened during the tightening of the other screws. Also secure the locking screw into place to cover the portion of the screw heads which are located at the ends of the plate. Failure to do so may result in screw loosening.

MRI Safety Information: Degas Anterior Cervical plate system has not been evaluated for safety and compatibility in the MR environment. Degas Anterior Cervical plate system has not been tested for heating, migration or image artifact in the MR environment. The safety of the Degas Anterior Cervical plate system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. Mixed metals such as titanium and stainless steel components should not be used together. Components of this system should not be used with components of any other system or any other manufacturer.

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 be experience 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.

CAUTION: Excessive torque on the threads of Screw may cause the threads to strip in the bone, reducing fi ation

Postoperati e

The physician’s postoperati e directions and arnings to the patie t and the corresponding patie t 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 components are complications which can occur as a result of excessive or early weight-bearing or excessive 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 such 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 activi-ties, especially lifting and twisting motions and any type of sport par-ticipation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
3. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physi-cal restriction in body motion.
4. If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. 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(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed roentgen-ographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. The Degas Anterior Cervical plate system implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and should be removed. In most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain. (2) Migration of implant position possibly resulting in injury, (3) Risk of additional inju y from post-operati e trauma. (4) Bending, loosening and/or breakage, which could make removal impracti al or difficult. (5) ain, discomfort, or abnormal sensations due o the presence of the device. (6) Possible increased risk of infection, and (7) Bone loss due to stress shielding. healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal, should be followed by adequate postoperative management to avoid fracture.

6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Degas Anterior Cervical plate system components should ever be reused under any circumstances.

Packaging, Labeling and Storage

-The implants are supplied non-sterile. They must be cleaned and sterilized, (see below)

-The implants are delivered in packages; these must be intact at the time of eceipt. All the legal information equired for this type of implants is given on the label of each package.

-The implants may be delivered as a complete set : implants and instrumentation a e set out on specially designed trays or in boxes which can be sterilized directly.

-Use care in handing and storage of implant components. Cutti , sharply bending, or scratching the surface can signifi antly reduce the strength and fatigue esistance of the implant system. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environments such as salt air, moisture, etc. Inspection and trial assembly a e recommended prior to surgery to determine if instrument components or implants have been damaged during storage or prior procedures.

Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids y lead to patie t 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, po ential leachables, and transmission of infectious a ents.

-Degas Anterior Cervical plate systems non sterile medical devices (implants and instrumentation) mu t be cleaned and sterilized before use according to the procedures detailed below.

-Symbols for use in the Labeling

SYMBOL TRANSLATION

LOT NUMBER	CATALOG NUMBER	QUANTITY
LOT	REF	QTY
NON-STERILE	SINGLE USE ONLY	See package insert for labeling limitation
NON STERILE		
Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.	MANUFACTURER	DATE OF MANUFACTURER
Rx Only		

CLEANING OF INSTRUMENTS:

Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Disassemble instruments with re-movable parts. Methods of cleaning Degas 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 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 pre-pared 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 and Decontaminatio

. All instruments and implants must fi st be cleaned using established hospital methods before sterilization and i troduction i to a sterile surgical field

. CAUTION: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.

. Implants removed from a patie t or that contact bodily tissues o fluids should n ver be reused.

. In a clean metal pan, prepare an enzymatic detergent bath according to the detergent manufacturers instructions.

• .Allow the devices to soak in enzymatic detergent bath for 20 minutes.

. While in detergent bath, using a soft bristled brush, gently clean the devices, paying attention to pivots, threads, recesses, crevices, cannula's and other difficult to clean areas, until all visible debris is removed.

. Remove the devices from the enzymatic detergent bath and rinse with tap water for a minimum of 1 minute.

. Prepare an enzymatic detergent bath in a sonicator.

. Ultrasonically clean the individual devices in the enzymatic bath for ten (10) minutes.

. Removed from sonicator and rinse the devices in DI water for a minimum of 1 minute.

. Dry the devices with a clean, soft cloth.

. Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed.

. Verify that the instruments are in operation condition

Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and they must not be used.

All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Reusable instrument of Cleaning Instructions

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 inclosed 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.

Preparation Before Cleaning

• 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. 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.Combination Manual/Automated - Enzymatic soak and scrub followed by an automated washer/disinfector cycle.

3.Automated cycle - Not recommended without manual pre-cleaning.

Manual Cleaning/Disinfection P ocedure

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

Table 2 Manual Cleaning steps

1. Completely submerge instruments in enzyme solution and allow 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 tap water for a minimum of 3 minutes. Throughly and aggressively flush lumens, holes and other difficult to reach areas.
3. Place prepared cleaning agents in a somication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50 kHz.
4. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
5. Repeat the sonication and rinse steps above.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

Combination Manual/Automated Cleaning Steps:

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 cycle:

i.Rinse 3 times using tap water for 30 seconds after wash using the enzymatic detergent in the ultrasound cleaner at 35-45°C for 3 minutes.

ii. Perform the ultrasound rinsing repeatedly subjected 3 times for 3 minutes using the purified water at 35-45°C.

iii. Dry at 100°C (±5°C) 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.

Inspection, esting & Mai tenance

1.Carefully inspect each instrument to ensure all visible blood and soil has been removed.

2.Inspect instrument 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 sue 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 representative for a replacement.

Sterilization Procedures

Unless noted otherwise on the package labeling, the Degas Anterior Cervical plate system components are provided non-sterile. These products need to be steam sterilized by the hospital using one of the following methods:

. Sterilization : recommended method to achieve a degree of sterility equal to at least 10^{-6} : autoclave at 132°C for 10 minutes(Steam, Pre-vacuum Cycle), Dry time : 55 minutes.

. The trays are to be used in conjunction with an FDA cleared sterilization wrap.

. This pre-vacuum sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizer and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Because of the potential risk of transmission of Creutzfeldt Jakob disease, some Health Care Authorities recommend sterilization according to these parameters, especially of surgical instruments that could come into contact with the central nervous system. Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

	Method	Method
Cycle	Gravity	Pre-Vacuum
Temperature	132°C(270°F)	132°C(270°F)
Exposure	15 minutes	4 minutes
Dry tim	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.

LIMITS ON REPROCESSING

Repeated processing cycles that include ultrasonic, mechanical wash-ing and sterilization have minimal effects on CTL Medical implants and instruments.

Recall

The guarantee is only applicable if the device is used in accordance with normal conditions as d fined in these in tructions and in conformity with the recommended surgical technique.

Guarantee

The guarantee is only applicable if the device is used in accordance with normal conditions, as d fined in these in truction and in conformity with the recommended surgical technique.

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