ENGLISH

CLARIANCE

Elegance® Anterior Cervical plate: Appliance, Fixation, Spinal Intervertebral Body

1. PURPOSE

The Elegance® Anterior Cervical plate is an anterior cervical plate system, intended for the stabilization of the cervical spine during bone fusion in the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is knowledgeable in the implant's material and surgical aspects and who has been trained as to its mechanical and material applications and limitations.

2. DESCRIPTION

The Elegance® Anterior Cervical plate is designed for use as a cervical plate system. It has a shape which restores the intervertebral height and lordosis. The Elegance® Anterior Cervical plate consists in a variety of shapes and sizes of cervical plates with rounded corners, featuring bone screw's holes, locking systems and bone screws. The plates go from one (1) to five (5) levels, and the screws are self-drilling or self- tapping, and fixed or variable. The fixation is provided by the bone screws inserted into the vertebral body by means of an anterior approach. The Elegance® plates, as well as the bone screws, are made of compliant ASTM F136 Titanium alloy. It is essential to insert the implants with the instrumentation specifically designed for this purpose. For more description of the instrumentation, read the technical documentation associated to the Elegance® Anterior Cervical plate. Detailed information concerning the surgical technique of the Elegance® Anterior Cervical plate is available upon request, please contact CLARIANCE or its local representative.

3. INDICATIONS

The Elegance® Anterior Cervical plate is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and imaging tests).
2. Spondylolisthesis.
3. Spinal stenosis.
4. Deformities (i.e., scoliosis, kyphosis, and/or lordosis).
5. Pseudoarthrosis.
6. Revision of previous surgery.

4. CONTRA-INDICATIONS

The Elegance® Anterior Cervical plate is not intended for posterior surgical implantation, for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. Contraindications include, but are not limited to:

· Any case not described in the indications.
· Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
· Any patient having inadequate bone quality or poor bone quality.

· Fever or leukocytosis, infection local to the operative site, signs of local inflammation.
· Any patient unwilling to co-operate with postoperative instructions, having a mental illness , alcoholism or drug abuse, a morbid obesity, pregnancy.
· Where attempted correction exceeds the limits of physiological conditions.

· Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication because this condition may limit the degree of obtainable correction.

· Suspected or documented allergy or intolerance to the constitutive materials, metal sensitivity, foreign body sensitivity, inadequate tissue coverage over the operative site.

· These devices must not be used for pediatric cases (age < 18 years), or where the patient still has general skeletal growth.

· A requirement for simultaneous anterior and posterior surgery.

· The presence of dysphagia before surgery.

IMPORTANT NOTE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include severe bone resorption and osteoporosis, osteomalacia.

5. SECONDARY AND POSSIBLE SIDE EFFECTS

All of the possible adverse events associated with spinal fusion surgery with or without instrumentation are possible but is not limited to the following list:

· Early or late loosening of any or all of the components, disassembly, bending, and/or breakage of components and/or migration of the components.

· Corrosion at the screw/locking interface contributing to breakage, and/or pseudoarthrosis.

· Cessation of any potential growth of the operated portion of the spine, loss of or increase in spinal mobility or function, inability to perform the activities of daily living.

· Bone loss or decrease in bone density, possibly caused by stress shielding, graft donor site complications including pain, fracture, collapse or wound healing problems.

· Foreign body (allergic) reaction to implants, debris, corrosion, metallosis, tumor formation, and/or autoimmune disease.

· Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain, implant or graft extrusion through the skin.

· Bursitis and tissue or nerve damage caused by improper positioning and placement of implants or instruments.

· Post-operative change in spinal curvature, loss of correction, height, and/or reduction, instability.

· Infection (paraspinal abscess), dural tears, pseudo-meningocele, fistula, persistent CSF leakage, meningitis.

· Discitis, arachnoiditis, and/or other types of inflammation.

· Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia.

· Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), C5 palsy, paraplegia, paraparesis, reflex deficits, irritation, muscle loss.

· Paresthesia, radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits, abnormal sensations.

· Scar formation possibly causing neurological compromise or compression around nerves and/or pain.

· Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or retropulsed graft.
· Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery, non-union (or pseudarthrosis), delayed union, and malunion.
· Hemorrhage, hematoma, hemothorax, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
· Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
· Dysphagia, esophageal irritation.
· Vocal cord injury (including hoarseness, sore throat, and vocal cord paresis).
· Urinary retention or loss of bladder control or other types of urological system compromise.
· Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
· Change in mental status, death.
Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

6. WARNINGS

· Do not use if package is opened or damaged

· The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, and other patient conditions, which may impact on the performance of the device.

· These devices are provided as single use only implants and are not to be reused or re-implanted regardless of an apparent undamaged condition. This is indicated on the labeling of the implant package by the next symbol.

· The reuse of single-use devices can have irreversible consequences on the security and the health of the patients (risk of contamination, risk of failure of the device, etc.). It is therefore strongly prohibited to reuse single use devices.

· The Elegance® plates and screws are provided in non-sterile state.

· If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant’s longevity.

· This device system is not intended to be the sole means of spinal support . This spinal implant cannot withstand body loads without the support of bone or cage. In this case, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

· Because different manufacturers employ different materials, varying tolerances, manufacturing specifications, and differing design parameters, components of the Elegance® Anterior Cervical plate should not be used in conjunction with components from any other manufacturer's implant systems. Any such use shall negate the responsibility of CLARIANCE for the performance of the resulting mixed component implant.

· Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

· Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

· Cervical plate device is intented to be implanted permanently. The lifetime of such devices varies from patient to patient. There are many factors affecting the outcomes and the lifetime of the device. These factors include, but are not limited to, patient's physical condition, patient's activity level and the progression of the disease.

7. CAUTION OF USE

- **PREOPERATIVE**

· 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,

· Only patients that meet the criteria described in the indications should be selected, correct selection of the implant is extremely important. An adequate inventory of sizes should be available at the time of surgery. The size of device for the case should be determined prior to beginning of surgery.

· Proper function of the surgical instruments should be verified prior to every surgical procedure. All instruments must be cleaned and sterilized before use.

- **INTRAOPERATIVE**

· The instructions in Elegance® Anterior Cervical plate surgical technique manual should be carefully followed.

· Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.

· Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.

- **POSTOPERATIVE**

· Detailed instructions on the use and limitations of the device should be given to the patient. It is recommended that a regular postoperative follow-up be undertaken to detect early signs of failure of the implants and to consider the action to be taken. The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion. It is important that immobilization of union is established and confirmed by x-rays, CT scans examination. If a non-union develops or if the components loosen, migrate, and/or break, the devices should be revised and/or removed immediately before serious injury occurs.

· Elegance® Anterior Cervical plate are intended to stabilize the operative area during the fusion process.

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

!USA

FOR US AUDIENCE ONLY

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

8. PACKAGING HANDLING AND STORAGE

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all instruments sets should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to CLARIANCE.

The Elegance® Anterior Cervical Plate requires minimal handling and must always be handled with the utmost care.

The Elegance® Anterior Cervical plate (in their original packaging) must be stored with care in a clean and dry place. Do not expose the Elegance® Anterior Cervical plate to radiations or extreme temperatures.

Should these requirements not be followed, reduced mechanical properties may occur which could lead to implant failure in some cases.

9. CLEANING – DECONTAMINATION – STERILISATION

All instruments must be cleaned before sterilization. Please follow the steps below:

1. Immediately following use, submerge the instruments or cover with a wet towel. Do not let biologically contaminated fluids dry on the instrument surfaces.
2. Some instruments may require disassembly to reach all surfaces. Disassemble where possible and appropriate. Refer to the Appendix of 99REPINS to obtain detailed instrument listing.
3. Rinse in tap water to remove soil.
4. Clean using an appropriate alkaline detergent solution diluted to the manufacturer’s instructions. Use cleaning tools such as brushes to thoroughly clean all instruments with careful attention to lumens and hard-to-reach areas.
5. Rinse with deionized tap water.
6. Carefully inspect the instruments and repeat the cleaning process if soil is visibly present.
7. Dry using clean towels or compressed air.
8. Visually inspect all instruments for damage, such as wear, cracks, deformation, or impaired functionality, such as loose joints. Any suspect instrument should be returned to Clariance.
9. Proceed to sterilization before use with parameter defined in the table below.

For more detailed instruction please refer you to the 99REPINS “Manual instruments for Spinal Surgery Instructions for care, Cleaning Maintenance, and Sterilization” 99REPINS “Manual instruments for Spinal Surgery Instructions for care, Cleaning Maintenance, and Sterilization”.

Method	Cycle	Temperature	Exposure time	Drying time[1]
Steam	Dynamic air removal	132°C (270°F)	4 Minutes	20 Minutes
Steam	Gravity	132°C (270°F)	15 Minutes	30 Minutes
Steam	Dynamic air removal	134°C (273°F)	18 Minutes	30 Minutes

[1]The minimum dry times were validated using sterilizers having vacuum drying capabilities. Drying cycles using ambient atmospheric pressure may require longer dry times. Refer to the sterilizer manufacturer's recommendations.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

The dynamic air removal sterilization cycle (18 minutes and 134°) is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications.

10. MRI SAFETY INFORMATION

The Elegance® Anterior Cervical plate has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Elegance® Anterior Cervical plate in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

11. 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, identification, durability, reliability, safety, effectiveness and/or performance, should notify CLARIANCE. Further, if any of the implanted Elegance® Anterior Cervical plate components does not meet any of its performance specifications or otherwise does not perform as intended, or is suspected of doing so, CLARIANCE should be notified immediately.

If any CLARIANCE product may have caused or contributed to the death or serious injury of a patient, CLARIANCE and the National Competent Authority where the incident has occurred should be notified as soon as possible by telephone 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 is requested from CLARIANCE.

FOR ALL INFORMATION OR COMPLAINTS, CONTACT:

In Europe	In USA
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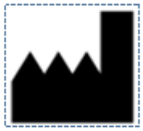
Symbol	Significance	Symbol	Significance
	Manufacturer		Lot number or batch code
	Catalog Number		Do not reuse / Single use only
	Attention: See package insert		Non-sterile
	Date of manufacture		Consult instructions for use or consult electronic instructions for use
	Do not use if packaging is damaged		Packaging is sensitive to humidity
	Sale of this device is restricted by or on the order of a physician		