DEVICE SYSTEM NAME

Cervical Plate System (Sterile)

DEVICE DESCRIPTION

The AUXEIN MEDICAL Anterior Cervical System consists of a range of bone plates and bone screws intended for use in anterior cervical fixation procedures. The system is designed to provide temporary stabilization of the cervical spine to support spinal fusion.

Fixation is achieved by inserting bone screws through the openings in the plate and into the vertebral bodies of the cervical spine. The anterior cervical plates incorporate an integrated anti-migration locking mechanism in the form of anti-migration caps intended to reduce the potential for screw back-out following implantation. These anti-migration caps cover and secure the heads of the bone screws within the plate construct, thereby enhancing fixation stability during the fusion process.

The anti-migration caps are supplied pre-assembled with the plate and are designed to allow visual confirmation of proper screw locking during implantation.

Associated surgical instruments are available to facilitate implantation of the device, including instruments for plate positioning, drilling, screw insertion, plate contouring, and engagement of the locking mechanism. The following is the list of variants:

1. **Asterius-Anterior Cervical Plate, Titanium**

The Asterius-Anterior Cervical Plate System is a low-profile cervical stabilization system designed to support anterior cervical fusion procedures. The system features a large graft window for enhanced graft visualization and an intuitive screw locking mechanism to minimize screw migration and maintain construct stability. The design supports restoration and maintenance of cervical disc height while promoting spinal fusion. The plates are fixed with the screws such as:

a. Asterius-3.5mm Cancellous Screw, Self-Tapping, (Cross Head), Titanium
b. Asterius-4.0mm Cancellous Screw, Self-Tapping, (Cross Head), Titanium
c. Asterius-3.5mm Cancellous Screw, Self-Drilling, (Cross Head), Titanium
d. Asterius-4.0mm Cancellous Screw, Self-Drilling, (Cross Head), Titanium
e. Asterius-3.5mm Cancellous Screw, Self-Tapping, (Hex Head), Titanium
f. Asterius-4.0mm Cancellous Screw, Self-Tapping, (Hex Head), Titanium
g. Asterius-3.5mm Cancellous Screw, Self-Drilling, (Hex Head), Titanium
h. Asterius-4.0mm Cancellous Screw, Self-Drilling, (Hex Head), Titanium

2. **REGEX-Anterior Cervical Plate, Level-I to Level-IV, Titanium**

The REGEX Anterior Cervical Plate is a low-profile anterior cervical fixation system designed for single and multi-level cervical stabilization procedures. The system incorporates fixed-angle and variable-angle screw options with an integrated self-locking anti-migration mechanism to provide stable fixation and prevent screw back-out. The system is available in Level I to Level IV plate configurations to accommodate different vertebral fixation levels. The REGEX consists of the following components:

a. 4.0mm REGEX-Bone Screw, Self-Drilling, Variable Angled, Titanium
b. 4.0mm REGEX-Bone Screw, Self-Drilling, Fixed Angled, Titanium
c. 4.5mm REGEX-Bone Screw, Self-Drilling, Variable Angled, Titanium

d. 4.5mm REGEX-Bone Screw, Self-Drilling, Fixed Angled, Titanium
e. 4.0mm REGEX-Bone Screw, Self-Tapping, Variable Angled, Titanium
f. 4.0mm REGEX-Bone Screw, Self-Tapping, Fixed Angled, Titanium
g. 4.5mm REGEX-Bone Screw, Self-Tapping, Variable Angled, Titanium
h. 4.5mm REGEX-Bone Screw, Self-Tapping, Fixed Angled, Titanium

MATERIALS

The Anterior Cervical System implant components are fabricated from medical grade titanium alloy described by such standards as ISO 5832-3:2021. This material is not compatible with other metal alloys. Do not use any of the Anterior Cervical System components with components from any other system or manufacturer.

INTENDED USE/PURPOSE

The Cervical Plate System implant components are temporary implants that are intended for anterior inter-body screw fixation of the cervical spine during the development of a cervical spinal fusion. The implantation of the Anterior Cervical System is via an anterior surgical approach.

INDICATIONS OF USE

The Cervical Plate System is intended for anterior inter-vertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Spondylolisthesis

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice of particular device must be carefully weighed against the patient's overall condition. The conditions listed below may preclude or reduce the chance of a successful outcome:

Absolute contraindication

- Active infectious process or significant risk of infection: Implantation under such conditions may exacerbate the infection and lead to serious complications including sepsis and implant failure.
- Fever or leukocytes: Fever or elevated leukocyte count may indicate the increased risk of surgical site infection and implant failure.
- Severe Osteopenia: Insufficient bone quality which does not provide fixation strength to which increases the risk of loosening and mechanical failure.
- Metal Sensitivity/ allergy: Known or suspected sensitivity or allergy to implant materials may result in adverse local or systemic reactions.

Relative contraindications

- Morbid Obesity: Patients with morbid obesity (typically BMI ≥ 35 kg/m²) are contraindicated due to excessive mechanical loading at the operative site. Increased body mass can result in implant failure, loosening, delayed healing, and higher risk of surgical complications such as infection and poor wound healing.
- Mental illness: Patients with uncontrolled psychiatric disorders or cognitive impairment that limits their ability to understand and comply with postoperative care, rehabilitation protocols, or weight-bearing restrictions are contraindicated, as non-compliance may result in implant failure and injury.
- Alcoholism or drug abuse: Chronic alcohol abuse may impair bone metabolism by increasing osteoclast activity, leading to poor bone formation, delayed union, or non-union of fractures.
- Pregnancy: Due to potential risks to the developing fetus and complications related to anesthesia, radiation exposure, and surgical stress may pose harm.

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 Cervical Plate System is only a temporary implant used for the correction and stabilization of the spine.

- This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- This system is also intended to be used to augment the development of spinal fusion by providing temporary stabilization.
- Women of child bearing potential should be warned of the potential risk to a fetus and should discuss other possible orthopedic treatments with their surgeon. This device system should not be used immediately before or during pregnancy.
- This device system is not intended to be the sole means of spinal support. Bone grafting (Autograft, Allograft, Synthetic Bone Grafts) must be part of the spinal fusion procedure in which the 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 Anterior Cervical System by the surgeon.
- 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. This device is not for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- Do Not Re-Use. Do not re-process. The device is not designed for re-processing. Reuse of the medical device intended for single use devices may lead to infection, degraded performance or a loss of functionality. The cleaning and disinfection / sterilization for re-processing of these single use devices has not been validated nor is any authentic information available. So reprocess of the single use device is not allowed.

TARGET PATIENT GROUP

The Anterior Cervical System is intended to be used in skeletally mature patients aged between 18-75 years. It is not be used in patients whose bones have not stopped growing. This device has not been

tested in pregnant women to determine if there is any effect on a developing fetus. This system has also not been studied in nursing mothers. This system should not be used immediately before or during pregnancy. Women of child-bearing potential should be advised not to get pregnant for one year following treatment with the device.

INTENDED USER GROUP

All qualified and well-trained/experienced Surgeons can use this device.

SURGEON NOTE

Although the surgeon is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION

- To be used by Qualified and Trained Surgeon Only.
- Federal (USA) law restricts this device to sale by or on the order of a physician.

MRI COMPATIBILITY

The Cervical Plate System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Cervical Plate System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

CLINICAL BENEFITS

If the device is used as per the labeling and recommended technique, it provides anterior interbody stabilization and supplemental fixation of the cervical spine during cervical fusion procedures and is expected to support the development of fusion, maintain spinal alignment and stability, reduce neck and/or arm pain, improve neurological function and functional status, and enhance quality of life, as assessed by appropriate clinical and radiological evaluations, including Visual Analogue Scale (VAS) and Neck Disability Index (NDI) scores.

PERFORMANCE CHARACTERSTICS

The cervical plate system has good load-bearing capacity (static and fatigue strength), Stiffness, rigidity, flexibility, it is also biocompatible for use and are capable of bending deformation and have sufficient strength to allow the insertion of fixing components.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The link to Summary of Safety and Clinical Performance (SSCP) will be updated in this Instructions for Use when the SSCP will be made available to the EUDAMED Database. Till the EUDAMED is completely functioning, the SSCP report can be found at Auxein's Website using https://www.auxein.com/sscp-report/.

POTENTIAL ADVERSE EVENTS

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

- Non-union
- Vertebral fracture
- Neurological injury
- Vascular injury
- Implant loosening, migration, or failure
- Loss of fixation
- Device component fracture Foreign body (allergic) reaction to implants, debris, corrosion products, and graft material, including metallosis, straining, tumor formation, and/or autoimmune disease
- Disassembly and/or bending of any or all of the components
- Infection
- Dysphagia
- Malunion
- Hemorrhage
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction
- Loss of or increase in spinal mobility or function

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

OTHER PREOPERATIVE, INTRAOPERATIVE AND POSTOPERATIVE WARNINGS ARE AS FOLLOWS

PREOPERATIVE

- Only patients that meet the criteria described in the indications should be selected. Patient conditions and/or predispositions such as those addressed in the contraindications mentioned above should be avoided.
- The type of construct to be assembled for the case should be determined before the beginning of 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.
- 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 Cervical Plate System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.

INTRAOPERATIVE

- Any available instruction manuals should be carefully followed.
- Always, extreme caution should be used around the spinal cord and nerve roots.
- Damage to nerves will cause loss of neurological functions.

- Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
- 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 neurological damage and bone necrosis.
- Before closing the soft tissues, all of the screws should be seated on the plate.
- Recheck the tightness of all screws after finishing making sure that none has loosened during the tightening of the other screws. Lock the anti-migration caps over the heads of the bone screws. Failure to do so may result in screw loosening.

POSTOPERATIVE

- The surgeon's postoperative directions and warnings to the patient and the corresponding patient compliance are crucial. Detailed instructions regarding the use and limitations of the cervical fixation device should be provided to the patient. The patient should be advised to strictly adhere to postoperative cervical spine precautions until solid bony fusion is achieved. Excessive or premature neck movements, inappropriate physical activity, or failure to comply with prescribed restrictions may result in complications such as bending, loosening, or breakage of the implant components. The risk of implant failure during the postoperative rehabilitation period may be increased in patients who are excessively active, non-compliant, debilitated, cognitively impaired, or otherwise unable to follow movement restrictions or properly utilize prescribed cervical support measures.

  The patient should be cautioned to avoid falls, sudden impacts, or abrupt movements of the cervical spine, as these may compromise the stability of the fixation construct and adversely affect the healing process.
- 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 alcohol during the bone healing process.
- The patient 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.
- 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 the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until a firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- The 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 may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, 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) Migration of implant position, possibly resulting in injury; (2) Risk of additional injury from postoperative trauma; (3) Bending, loosening and breakage, which could make removal impractical or difficult; (4) Pain, discomfort, or abnormal sensations due to the presence of the device; (5) Possible increased risk of infection; (6) Bone loss due to stress shielding; and

- While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should consider 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.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the Cervical plate System components should never be reused under any circumstances. Reuse may lead to infection and cross infection. The reuse of implants after re-sterilization may not result in the same responses.
- Orthopedic surgeries do not generally involve major risks and complications. Orthopedic Surgeons are properly trained to avoid potential difficulties which might occur during an intervention, as well as to efficiently correct such problems if they appear. However, some of the risks and complications which may accompany an orthopedic surgical procedure are:
  - **Postoperative infections:** In order to avoid this complication, patients will be administered antibiotics before, during and after the surgery.
  - **Bleeding**
  - **Blood clots:** They may occasionally appear after orthopedic surgery. Blood clots can be avoided with appropriate medication and physical exercise.
  - **Blood vessel damage:** This complication may appear if blood vessels located in proximity to the implant are affected during the procedure.
  - **Allergic reactions:** The patient might experience an allergic reaction to the metal components used to fix the implant (titanium, etc.)

PACKAGING

Packages for each component should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage before use. Damaged packages or products should not be used, and should be returned to AUXEIN MEDICAL PVT LTD.

STERILIZATION

Cervical Plate System is supplied Sterile. A sterility assurance level SAL 10^{-6} was achieved using gamma irradiation sterilization with minimum dose of 25kGy. Check the integrity of the packaging and labeling before opening the pack.

STORAGE

Store the implants at a dry place. Care should be taken in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct and the temperature range shall be 10℃ to 30℃.

DISPOSAL

The Orthopedic implant is to be disposed off as per the Hospital and Regulatory norms.

PRODUCT COMPLAINTS

Customers or users of products, who have any complaints or who have experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the Manufacturer, AUXEIN MEDICAL, EU Representative or Competent Authority. Further, if any of the implanted 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 Manufacturer, EU Representative or Competent Authority should be notified immediately.

If any AUXEIN MEDICAL's product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the Manufacturer, EU Representative or Competent Authority should be notified Immediately By Telephone, Fax Or Written Correspondence. When filing a complaint, please provide the component(s) name, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

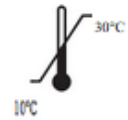
FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact your representative or distributor or contact the manufacturers direct at https://www.auxein.com/ where IFU, Surgical Technique and Catalogue are also available

DETAILS OF SYMBOL WITH LABELING

Symbol	Symbol Title	Description	Standard Title	Reference Number
	Date of Manufacture	Indicates the date when the medical device was manufactured.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.3
	Manufacturer	Indicates the medical device manufacturer	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.1

EU REP	Authorized representative in the European community	Indicates the authorized representative in the European Community/European Union	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.2
CC	Country of manufacture	To identify the country of manufacture of products	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.11
REF	Reorder Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.6
CE	Conformité Européene (European Conformity)	Signifies European technical conformity.	EU MDR 2017/745.	MDR 2017/745 (Annex XII, Article 20)
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.5
2	Do Not Reuse	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.4.2
2 STERILIZE	Do not re-sterilize	Indicates a medical device that has already subjected to a sterilization process, so do not re-sterilize.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.6
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.4
	Keep away from the sunlight	Indicates a medical device that needs protection from light sources	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.2

	Consult instructions for use	Indicates the need for the user to consult the instructions for use	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.3
	Do not use if package is damaged.	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.8
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.4
	Double sterile barrier system	Indicates two sterile barrier systems	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.12
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.7
	Quantity	Indicates quantity of medical devices contained within the packaging.	N/A	N/A
	Prescription only	The symbol for Prescription Device Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	N/A	21 CFR 801.15 ad 21 CFR 801.109 ((c) (1) (i) (F) (b) (1))
	Medical device	Indicates the item is a medical device	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.7.7
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.7.10

	Caution	Indicates that caution is necessary when operating the device.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.4.4

CE 2460

Notified Body: DNV Product Assurance AS
Notified Body Number: 2460
Address Notified Body: Veritasveien 1, 1363 Høvik, Norway
Certificate Number:

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Revision History Table:

S. No.	Document No	Rev. No.	Description of Revision	Effective date	Prepared by	Approved by
1.	AMPL-IFU-ACS/S-008	00	Initially Released	21-10-2024		
2	AMPL-IFU-ACS/S-008	01	Updated the symbol table, format.	02-01-2026		

3.	AMPL-IFU-ACS/S-008	02	Updated the Device description as per LOF .	28-05-2026