SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR CERVICAL PLATE SYSTEM

Table of Contents

1. The identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN.....3
2. The intended purpose of the device and any indications, contraindications and target populations. 8
3. Description of the device.....9
4. Information on any residual risks and any undesirable effects, warnings and precautions. 21
5. The summary of clinical evaluation and relevant information on post-market clinical follow-up. 23
6. Possible diagnostic or therapeutic alternatives. 26
7. Suggested profile and training for users. 27
8. Reference to any harmonized standards and CS applied. 28
9. Revision history 31
A summary of the safety and clinical performance of the device, intended for patients, is given below:.....33
Device identification and general information 33
Intended use of the device.....34
Device description 35
Risks and Warnings.....38
Summary of clinical evaluation and post-market clinical follow-up.....39
7. Suggested training for users.....46

The following information is intended for users/healthcare professionals.

1. The identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN.

Basic UDI-DI:

	Titanium Non-Sterile	**Titanium Sterile**
Asterius-3.5mm Cancellous Screw, Self-Tapping, (Cross Head), Titanium	08903993008CPS001THT	08903993008CPS001TSVC
Asterius-4.0mm Cancellous Screw, Self-Tapping, (Cross Head), Titanium	08903993008CPS002THW	08903993008CPS002TSVH
Asterius-3.5mm Cancellous Screw, Self-Drilling, (Cross Head), Titanium	08903993008CPS003THZ	08903993008CPS003TSVN
Asterius-4.0mm Cancellous Screw, Self-Drilling, (Cross Head), Titanium	08903993008CPS004TJ4	08903993008CPS004TSVT
Asterius-3.5mm Cancellous Screw, Self-Tapping, (Hex Head), Titanium	08903993008CPS005TJ7	08903993008CPS005TSVY
Asterius-4.0mm Cancellous Screw, Self-Tapping, (Hex Head), Titanium	08903993008CPS006TJA	08903993008CPS006TSW5
Asterius-3.5mm Cancellous Screw, Self-Drilling, (Hex Head), Titanium	08903993008CPS007TJD	08903993008CPS007TSWA
Asterius-4.0mm Cancellous Screw, Self-Drilling, (Hex Head), Titanium	08903993008CPS008TJG	08903993008CPS008TSWF
REGEX-Anterior Cervical Plate, Level-I, Titanium	08903993008CPS009TJK	08903993008CPS009TSWL
REGEX-Anterior Cervical Plate, Level-II, Titanium	08903993008CPS010THV	08903993008CPS010TSVE
REGEX-Anterior Cervical Plate, Level-III, Titanium	08903993008CPS011THY	08903993008CPS011TSVK
REGEX-Anterior Cervical Plate, Level-IV, Titanium	08903993008CPS012TJ3	08903993008CPS012TSVQ
4.0mm REGEX-Bone Screw, Self-Drilling, Variable Angled, Titanium	08903993008CPS013TJ6	08903993008CPS013TSVV
4.0mm REGEX-Bone Screw, Self-Drilling, Fixed Angled, Titanium	08903993008CPS014TJ9	08903993008CPS014TSW2
4.5mm REGEX-Bone Screw, Self-Drilling, Variable Angled, Titanium	08903993008CPS015TJC	08903993008CPS015TSW7
4.5mm REGEX-Bone Screw, Self-Drilling, Fixed Angled, Titanium	08903993008CPS016TJF	08903993008CPS016TSWC
4.0mm REGEX-Bone Screw, Self-Tapping, Variable Angled, Titanium	08903993008CPS017TJJ	08903993008CPS017TSWH
4.0mm REGEX-Bone Screw, Self-Tapping, Fixed Angled, Titanium	08903993008CPS018TJM	08903993008CPS018TSWN

4.5mm REGEX-Bone Screw, Self-Tapping, Variable Angled, Titanium	08903993008CPS019TJQ	08903993008CPS019TSWT
4.5mm REGEX-Bone Screw, Self-Tapping, Fixed Angled, Titanium	08903993008CPS020TJ2	08903993008CPS020TSVM
Asterius-Anterior cervical Plate	08903993008CPS021TJ5	08903993008CPS021TSVS

SRN: IN-MF-000018837

The Cervical plate System includes the following as listed below:

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

The Asterius-Anterior Cervical Plate 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:

- Asterius-3.5mm Cancellous Screw, Self-Tapping, (Cross Head), Titanium
- Asterius-4.0mm Cancellous Screw, Self-Tapping, (Cross Head), Titanium
- Asterius-3.5mm Cancellous Screw, Self-Drilling, (Cross Head), Titanium
- Asterius-4.0mm Cancellous Screw, Self-Drilling, (Cross Head), Titanium
- Asterius-3.5mm Cancellous Screw, Self-Tapping, (Hex Head), Titanium
- Asterius-4.0mm Cancellous Screw, Self-Tapping, (Hex Head), Titanium
- Asterius-3.5mm Cancellous Screw, Self-Drilling, (Hex Head), Titanium
- Asterius-4.0mm Cancellous Screw, Self-Drilling, (Hex Head), Titanium

2. **Regex Anterior Cervical Plate System, 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:

- REGEX-Anterior Cervical Plate, Level-I, Titanium
- REGEX-Anterior Cervical Plate, Level-II, Titanium
- REGEX-Anterior Cervical Plate, Level-III, Titanium
- REGEX-Anterior Cervical Plate, Level-IV, Titanium

- 4.0mm REGEX-Bone Screw, Self-Drilling, Variable Angled, Titanium
- 4.0mm REGEX-Bone Screw, Self-Drilling, Fixed Angled, Titanium
- 4.5mm REGEX-Bone Screw, Self-Drilling, Variable Angled, Titanium
- 4.5mm REGEX-Bone Screw, Self-Drilling, Fixed Angled, Titanium
- 4.0mm REGEX-Bone Screw, Self-Tapping, Variable Angled, Titanium
- 4.0mm REGEX-Bone Screw, Self-Tapping, Fixed Angled, Titanium
- 4.5mm REGEX-Bone Screw, Self-Tapping, Variable Angled, Titanium
- 4.5mm REGEX-Bone Screw, Self-Tapping, Fixed Angled, Titanium

Details Regarding the device are provided in below table:

Device Trade Name:	**Cervical Plate System**		
Manufacturer Details	**Name & Address of Manufacturer:** Auxein Medical Pvt. Ltd. **Manufacturing Unit:** Plot No. 168-169-170, Phase IV, Kundli Industrial Area, HSIIDC, Sector-57, Sonipat, Haryana– 131028, India **Phone:** +91-9910643638 **Email: info@auxeinmedical.com** **Website:** www.auxein.com		
Manufacturer's SRN	IN-MF-000018837		
EMDN Code	P09070301		
Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, Cervical Plate System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	**Initial Certificate No.** 4825-2014-CE-IND-NA **Re certification Certificate No.**: 10000363901-PA-NA-IND Rev 3
Year when the first certificate (CE) was issued covering the device	2014		
Raw Materials of Implants	The Raw Materials used for manufacturing the Implants consists of Titanium alloy Ti-6AL-4V as per ISO 5832-3:2021.		
Conformity Assessment Route	Conformity Assessment of Class IIb devices has been conducted as per Article 52 (4), Chapter I, II and III of Annex IX of EU MDR 2017/745.		

USFDA Approved	Not Applicable
Risk Class	IIb {According to REGULATION (EU) 2017/745 (MDR) OF THE EUROPEAN PARLIAMENT, Annex VIII,Chapter-3, Rule 8 - Implantable devices and long-term surgically invasive devices (>30 days)}are in Class IIb unless they are intended: 1. Are intended to be placed in the teeth, in which case they are classified as class IIa; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Cervical plate intended to be placed in Cervical bone to treat abnormality/trauma injury not intended for teeth.* 2. Are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Cervical plate comes in contact with the Cervical bone. Thus, it does not come in contact with the heart, the central circulatory system or the central nervous system.* 3. Have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Cervical Plate System is made up of medical grade metallic alloy. Metallic alloy does not achieve its intended use by biological effect or by absorption.* 4. Are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Cervical Plate System is made up of medical grade metallic elements. These metallic elements have high metallic bonds that do not undergo chemical change in the body.* 5. Are intended to administer medicinal products, in which casethey are classified as class III; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Cervical plate implants made up of metal alloys to provide support for the Cervical*

	abnormality/trauma injury. The system is not intended to administer medicinal products. 6. Are active implantable devices or their accessories, in whichcases they are classified as class III; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification: 'Active Device'*** *means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. The Cervical Plate System does not depend on a source of energy.* 7.Are breast implants or surgical meshes, in which cases they areclassified as class III; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Cervical Plate System treats Cervical abnormality/trauma injury. Not intended as breast implants or surgical meshes.* 8. Are total or partial joint replacements, in which case they are classified as class III, except ancillary components such as screws, wedges,plates and instruments; or; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Cervical Plate System treats Cervical abnormality/trauma injury. Not intended for Total or Partial JointReplacements.* 9.Are Spinal Disc Replacement Implants or are implantable devices that come into contact with the Spinal Column, in which case they are classified as class III except components such as screws, wedges, plates and instruments: ***Applicable/ Not Applicable:*** *Applicable* ***Justification:*** *The Cervical Plate System is an implantable device to treat Cervical abnormality/trauma injury. The Plate come into contact with cervical spine to treat abnormality and trauma injuries.*
Authorized Representative Name and Address	**Name:** CMC Medical Devices & Drug S.L **Address:** 29015 Málaga, Spain
Authorized Representative SRN	ES-AR-000000293
Notified Body Name and Single	**Name:** DNV Product Assurance AS

Identification Number	**Single Identification Number:** 2460

2. The intended purpose of the device and any indications, contraindications and target populations.

The Indications, Contraindication and Intended Patient Population related information is provided in below table:

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.
Intended Patient Population	Skeletelly mature male and female Subjects aged between 18-75 years.
Intended Users	The Cervical Plate System is recommended to be used by only well-trained, certified and experienced surgeons.
Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
Use	For Single Use only
Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
Biocompatibility	The devices covered in the Cervical Plate System are Bio-compatible. Biocompatibility of the devices is tested as per ISO 10993-1 series of International Standard.

3. Description of the device

A Detailed device description is given in below table.

ASTERIUS ANTERIOR CERVICAL SYSTEM		
1.	Device Name	Asterius- Anterior Cervical Plate
	Image	
	Plate Length	22.5 to 70mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

1.a	Device Name	Asterius-3.5mm Cancellous Screw, Self-Tapping, (Cross Head)
	Image	
	Length	12 to 22mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
1.b	Device Name	Asterius-4.0mm Cancellous Screw, Self-Tapping, (Cross Head)
	Image	
	Length	12 to 22mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
1.c	Device Name	Asterius-3.5mm Cancellous Screw, Self-Drilling, (Cross Head)
	Image	
	Length	12 to 22mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

1.d	Device Name	Asterius-4.0mm Cancellous Screw, Self-Drilling, (Cross Head)
	Image	
	Length	12 to 22mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
1.e	Device Name	Asterius-3.5mm Cancellous Screw, Self-Tapping, (Hex Head)
	Image	
	Length	12 to 22mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
1.f	Device Name	Asterius-4.0mm Cancellous Screw, Self-Tapping, (Hex Head)
	Image	
	Length	12 to 22mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
1.g	Device Name	Asterius-3.5mm Cancellous Screw, Self-Drilling, (Hex Head)

	Image	
	Length	12 to 22mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
1.h	Device Name	Asterius-4.0mm Cancellous Screw, Self-Drilling, (Hex Head)
	Image	
	Length	12 to 22mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
REGEX ANTERIOR CERVICAL PLATE		
2.	Device Name	REGEX Anterior Cervical Plate
	Image	
	Length (mm)	12 to 24 (Level I), 26 to 46 (Level II), 40 to 67 (Level III), and 60 to 84 (Level IV)

	Level	I, II, III, and IV
	Directional Configuration (Left/Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
2.a	Device Name	4.0mm REGEX-Bone Screw, Self-Drilling, Variable Angled
	Image	
	Length of Screw	10 to 20mm
	Directional Configuration (Left/Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
2.b	Device Name	4.0mm REGEX-Bone Screw, Self-Drilling, Fixed Angled
	Image	
	Length of Screw	10 to 20mm
	Directional Configuration (Left/Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
2.c	Device Name	4.5mm REGEX-Bone Screw, Self-Drilling, Variable Angled
	Image	
	Length of Screw	12 to 20mm

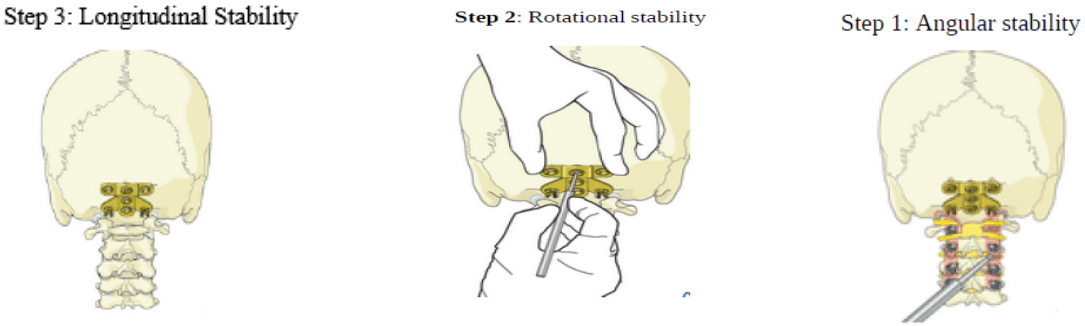
	Directional Configuration (Left/Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
2.d	Device Name	4.5mm REGEX-Bone Screw, Self-Drilling, Fixed Angled
	Image	
	Length of Screw	12 to 20mm
	Directional Configuration (Left/Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
2.e	Device Name	4.0mm REGEX-Bone Screw, Self-Tapping, Variable Angled
	Image	
	Length of Screw	10 to 20mm
	Directional Configuration (Left/Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021
2.f	Device Name	4.0mm REGEX-Bone Screw, Self-Tapping, Fixed Angled
	Image	
	Length of Screw	10 to 20mm
	Directional Configuration (Left/Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

2.g	Device Name	4.5mm REGEX-Bone Screw, Self-Tapping, Variable Angled
	Image	
	Length of Screw	12 to 20mm
	Directional Configuration (Left/Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
2.h	Device Name	4.5mm REGEX-Bone Screw, Self-Tapping, Fixed Angled
	Image	
	Length of Screw	12 to 20mm
	Directional Configuration (Left/Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

Other details of the Cervical Plate System:

Device Compliance to regulation		We are proposing the Cervical Plate System as per the compliance to European Union Medical Device Regulation (EU MDR 2017/745).
1.	DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES	
1.1	Device Description and Specification	
a.	Product/Trade Name	Cervical Plate System
	General Description	The Cervical Plate System is a range of devices designed to treat deformity, stabilize and strengthen the spine in patients suffering from degenerative disc disease, spinal stenosis and fracture. Each device is made from a medical grade Titanium Alloy (Ti-6Al-4V ELI).
	Intended Purpose	The Cervical Plate System is intended for anterior inter-body screw fixation of the cervical spine during the development of a cervical spinal fusion.

	Intended Users	The Cervical Plate System is recommended to be used by only well-trained, certified and experienced surgeons.
b.	Intended Patient Population	Skeletelly mature male and female Subjects aged between 18-75 years.
	Medical Conditions to be diagnosed, treated and/or monitored	The Cervical Plate System is used to treat the degenerative disorders of the cervical spine, tumors, trauma, and deformity. Specifically designed cervical plate intended for cervical spinal fusion that provides strong fixation and restores the bone fragments.
	Patient Selection Criteria	**Inclusion Criteria**: Male and female Subjects aged between 18-75 years. **Exclusion Criteria**: Infection: active local or Systemic infection to the operative site, morbid obesity (BMI >35 kg/m^2), mental disorders or currently on psychiatric treatment, Alcoholics and or drug abusers, patients with metabolic bone disease, Severe osteopenia, Metal sensitivity/allergies. Pregnant women or those planning pregnancy

c.	Principles of Operation	Cervical Plate System works on the AO Principle of Fracture Management. The key concept of fracture management involves: 1. Stability 2. Alignment 3. Function 4. Biology The Auxein's Cervical Plate System aims for stabilization of the cervical bone anatomy by balancing the spine in three dimensions which helps preservation and restorations of function to prevent disability. The proper fixation of the plate preserves the biology that provides better tissue healing and neural protection by following surgical technique provided by the manufacturer.
	Mode of Action	The plate fixed to the bone exerts compression, bending forces. Locking of the plate by employing screws along its shaft prevents fixation failure between the bones. The plate fixed with this approach maintains anatomical stabilization and anatomical reduction of the fractured bone and promotes the bone's healing.
	Scientifically demonstration of Principle of Operation	
d.	Rationale for considering as a Medical device	**As per Article 2 (1) of EU MDR 2017/745** 'Medical Device' means any instruments, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

		Thus, the Cervical Plate System is an implant used in humans for medical purposes to treat Cervical abnormality/trauma injury. **Applicable/Non-Applicable defines applicancy of the statement:** a) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease- **Not Applicable** ***Rationale for Non Applicability*** *The Cervical Plate System is an implant used for the treatment of Cervical abnormality/trauma injury. Thus, it is not used for diagnosis, prevention, monitoring, prediction, prognosis or alleviation of disease.* b) diagnosis, monitoring, treatment, alleviation of, or compensationfor an injury or disability- **Applicable** ***Rationale for Applicability*** *The Cervical plate system is an implantable device used for the treatment of Cervical abnormality/trauma injury.* c) investigation,replacement or modification of the anatomy or of a physiological or pathological processor state- **Not Applicable** ***Rationale for Non Applicability*** *The Cervical plate system is intended to treat Cervical abnormality/trauma injury in order to maintain its anatomical state. The Plate is not meant for investigation, replacement or modification of the anatomy or of a physiological or pathological state purpose of use.* d) providing information by means of in vitro examination of specimens derived from the human body, including organs, blood and tissue donations- **Not Applicable** ***Rationale for Non Applicability*** *Cervical plate is made up of metal alloy and employed to fix Cervical abnormality/trauma injury. This*

		system does not contain the In-vitro examination of specimens derived from the human body, including organ, blood and tissue donations. *The **device does not** achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. Hence, the Cervical Plate System is considered to be a medical device.* ***The following products shall also be deemed to be medical devices*** e) Devices for the control or support of conception- **Not Applicable** ***Rationale for Non Applicability*** *The Cervical Plate System is used to stabilize Cervical abnormality/trauma injury. This device is not for the control or support of conception.* f) Products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article1(4) and of thosereferred to in the first paragraph of this point-**Not Applicable** ***Rationale for Non Applicability*** *The Cervical Plate System is intended for Cervical abnormality/trauma injury. The system is not meant for cleaning, disinfection or sterilization of device.*
e.	Novel Features	The Cervical Plate System comprises of already existing devices approved in EU market under the regulation MDD 93/42/EEC. Since the device was placed on the market, there are no changes or modifications in device related to raw material, design, manufacturing process (coolants, lubricants, chemicals), intended use, post processing materials, etc.
f.	Description of key functional elements	The Cervical Plate System comprises of functional elements as : ● Screws **The description of the functional element used with Plate to fix the fracture enlisted below.** ***Screw*** ○ It is intended to be used for the implantation of any type of internal Orthopedic Fixation System.

		○ It is used for internal orthopaedic fracture fixation by being screwed into bone to hold Plate with cervical bone. ○ In the Cervical Plate System various types of screws are included like cancellous screw (self tapping & self drilling), Regex bone screw (variable angled screw and fixed angled screw).
g.		
	Sterility	All Products covered in Cervical Plate System are supplied in either Non-sterile or in Sterile state. Sterile implants which are placed on the market are sterilized by using Gamma Irradiation Sterilization (SAL 10^{-6}). The Non-Sterile implants which are placed on market are to be sterilized at 121 degree centigrade for 15 minutes (Moist Heat Sterilization/Autoclave Sterilization) as instructed in IFU for Non-sterile devices before implantation.
	Radioactivity	Products covered in Cervical Plate System are metal products and does not emit any ionizing or non-ionizing radiation.
	Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
	Use	For Single Use only
	Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
	Biocompatibility	The devices covered in the Cervical Plate System are Bio-compatible. Biocompatibility of the devices is tested as per ISO 10993 series of International Standard.
	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.
1.2	Reference to Previous and Similar Generations of the device	
a.	CE Mark (Legacy device)	CE Approved by **DNV (2460)** under MDD 93/42/EEC **Initial Certificate No.** 4825-2014-CE-IND-NA **Re certification Certificate No.**: 10000363901-PA-NA-IND Rev 3
	USFDA Approved	Not Applicable

b.	Similar devices available in Union or international market.	The Similar devices available on the European Union or International Market enlisted below: DePuy Synthes: Anterior Cervical Plate System Vectra (CE 0123) Medtronic: ZEPHIR™ Anterior Cervical Plate System (CE 0123) Precision Spine: Slimpicity (CE 2797)

4. Information on any residual risks and any undesirable effects, warnings and precautions.

Residual risks and undesirable effects

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

Quantitative Risk:

Device Name	Total No. of Patients	No. of Patients Having Complications	Summary of Benefit–Risk Analysis for Safety Parameters
Cervical Plate	1029	123	Large patient population (n=1029) provides a strong clinical evidence base for safety and performance evaluation. Overall complication rate ≈ 11.94%. Reported complications commonly include dysphagia, adjacent segment degeneration, implant-related irritation, screw loosening, infection, and non-union in some cases. Despite the identified risks, the clinical benefits outweigh the associated risks due to reliable cervical stability, effective fusion support, maintenance of spinal alignment, and favorable post-operative outcomes. Cervical Plate systems remain a widely accepted and clinically established treatment option for cervical spine surgical management.
Rod & Screw	226	9	Overall complication rate ≈ 3.96%. Reported complications may include screw loosening, hardware failure, infection, and adjacent segment stress. However, the system provides strong biomechanical stability, effective fixation, and favorable surgical outcomes. The benefits outweigh the identified risks when used according to intended surgical indications.
Artificial Disc	927	89	Overall complication rate ≈ 9.56%. Common complications include implant migration, heterotopic ossification, persistent neck pain, and revision surgery in selected cases. However, the device offers advantages such as motion preservation, reduced adjacent segment degeneration risk, and improved functional mobility. Clinical benefits outweigh the associated risks in appropriately selected patients.
Expandable Cage	191	20	Overall complication rate ≈ 10.47%. Common complications include cage subsidence, migration, non-union, and implant-related complications. Despite these risks, the device provides restoration of disc height, spinal stability, and effective load distribution. Benefits outweigh risks when used according to intended purpose and surgical technique.
Interbody Cage	199	15	Overall complication rate ≈ 7.52%. Reported complications may include cage migration, subsidence, infection, and delayed fusion. However, the device provides effective structural support, promotes fusion, and assists in maintaining cervical alignment. The overall clinical

			benefits outweigh the identified risks, supporting acceptable safety and performance outcomes.
PMCF Study	30	0	No complications were reported during the PMCF study. Clinical outcomes demonstrated satisfactory safety and performance of the Cervical Plate system. The benefit–risk profile remains favorable, confirming that the clinical benefits significantly outweigh the associated residual risks when used as intended.

Warning & 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.

1. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
2. This system is also intended to be used to augment the development of spinal fusion by providing temporary stabilization.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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.

5. The summary of clinical evaluation and relevant information on post-market clinical follow-up.

Prospective Clinical Evaluation:

Prospective Study of the legacy device has been approved by the ethics committee.

Identity of the investigation/study: A Prospective, Single Arm, Post Market Clinical Follow- up (PMCF) study to evaluate the Safety and Performance of Cervical System.

Name or Code of Study	**Completed (Yes/No)**	**Name of countries in study is conducted**	**No. of patients enrolled /and the target No.**	**No. of serious incidents**	**Serious incident rate (%)**	**No. of deaths**
	Ongoing	**INDIA**	**16/30**	**0**	**0**	**0**
Study Title	A Prospective, Single Arm, Post Market Clinical Follow- up (PMCF) study to evaluate the Safety and Performance of Cervical System.					
CTRI Number	CTRI/2024/10/074836					
CTRI Registration Date	07/10/2024					
Number of study sites	2					
Name of Study Sites	Stavya spine Hospital and Research institute, Ahmedabad, Gujarat 380006, India			Research institute, Ahmedabad, Gujarat 380006, India		
No. of Patients enrolled	16					

Study design: A Prospective, Single Arm, Post Market Clinical Follow-up (PMCF) study to evaluate the Safety and Performance of Cervical System. This longitudinal study was designed as a single-arm study. The target population for this research comprised both males and females aged 18 years or older at the time of surgery. The study aimed to recruit a total of 60 subjects due for cervical surgery viz. deformity correction, stabilize and strengthen the cervical spine region in patients suffering from degenerative disc disease, damaged or unstable vertebral body and fractures.

Inclusion criteria

1. Patients presenting to Orthopaedic OPD/emergency, requiring treatment with anterior cervical plate or/and cage.
2. Male and female, aged between 18- 75 years

Exclusion criteria

1. Patients with active local or systemic infection.
2. Patients with morbid obesity (BMI >35 kg/m2)
3. Patients with mental disorders or currently on psychiatric treatment.

4. Alcoholics and or drug abusers.
5. Patients with metabolic bone disease.
6. Severe osteopenia
7. Metal sensitivity/allergies
8. Pregnant women or those planning pregnancy during study.

Primary Objective

1. 1. To assess performance of cervical system by radiological evaluation.
2. To evaluate the improvement in pain through Visual Analogue Scale (VAS).

Secondary Objective

1. 1. To assess the improvement in quality of life through Neck disability index (NDI).
2. To record and analyze complications including serious adverse events.

Primary Endpoints

1. Radiological evaluation by X-rays will be done to assess the performance of implants at each post-operative follow up visit (6 week, 6 Month, and 12 Month).
2. To evaluate improvement in pain, VAS score will be recorded at each post-operative follow up visit (6 week, 6 Month, and 12 Month).

Secondary Endpoints

1. To evaluate improvement in quality of life, NDI will be recorded at each post- operative follow up visit (6 week, 6 Month, and 12 Month).
2. To ascertain the safety of implants, post-operative complications including serious adverse events will be recorded at each follow up visit (6 week , 6 Months, and 12 Months).

Population Detail:

Summary of Demographics and Baseline Characteristics

Characteristics	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (BMI)
Mean	51.5	67.43	166.5	24.51
Range	37 - 75	48 - 90	150 - 178	18.4 - 31.2

Median	53	66	168	24.55

Gender distribution of study subjects

Male	7
Female	9

6. Possible diagnostic or therapeutic alternatives.

Initial evaluation of the cervical fracture include a range of imaging and management strategies selected according to fracture characteristics, stability, neurological status, and patient-specific factors. Diagnostic evaluation commonly begins with plain radiographs (anteroposterior, lateral, and open-mouth odontoid views), while computed tomography (CT) is the preferred modality for detailed assessment of fracture pattern, alignment, and stability. Magnetic resonance imaging (MRI) is an important adjunct for evaluating spinal cord injury, ligamentous disruption, intervertebral disc involvement, and occult fractures not clearly visualized on radiographs or CT, and in selected neurologically intact patients, dynamic flexion–extension radiographs may be used in the subacute phase to assess residual instability. Therapeutic alternatives range from non-surgical management, including immobilization with a rigid cervical collar, cervicothoracic orthosis, or halo vest for stable fractures without neurological deficit, to surgical management for unstable fractures, progressive deformity, neurological impairment, or failure of conservative treatment. Surgical options include anterior approaches (such as anterior cervical plating or corpectomy with fusion), posterior stabilization (including lateral mass or pedicle screw fixation), or combined anterior–posterior techniques, chosen based on fracture morphology and stability requirements, with the goals of achieving stable fixation, decompression when indicated, correction of deformity, and early mobilization.

Treatment

1. Conservative (Non-Surgical) Treatment

For stable fractures that do not involve the spinal cord or significant misalignment, non-surgical treatment is typically sufficient.

A. Immobilization:

- **Cervical Collar or Brace:** A neck brace or cervical collar is often used to keep the neck stable and restrict movement, allowing the fracture to heal. The duration of use varies depending on the severity of the fracture but can range from several weeks to months.

- **Halos:** In some cases, a halo vest may be used. This involves a metal ring (halo) attached to the skull with pins, which is then connected to a chest vest. This provides more rigid immobilization and is typically used in more severe fractures when the risk of spinal cord injury is higher.

B. Pain Management:

- Over-the-counter pain relievers like acetaminophen or NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) are typically prescribed for pain control.
- Muscle relaxants may also be given to reduce muscle spasms in the neck.
- Opioid pain medications might be prescribed for short-term use in more severe pain cases, though these are used with caution due to the potential for addiction or side effects.

C. Physical Therapy:

- Once the acute phase of the injury has passed, physical therapy may be initiated to help improve neck mobility, strengthen muscles, and reduce stiffness.
- This will typically begin with gentle range-of-motion exercises and progress as healing occurs.

D. Monitoring:

- Regular follow-up visits with the doctor to monitor healing through X-rays or CT scans are common to ensure proper alignment and that the fracture is healing as expected.

2. Surgical Treatment

Surgical treatment options for cervical spine indications depend on the pathology, severity of symptoms, neurological involvement, spinal stability, and patient health status. Below are commonly used surgical options for the listed cervical conditions:

- **Cervical Plate and Screws:** Used in anterior cervical fusion procedures to provide immediate stability and maintain alignment after disc or vertebral body removal.
- **Interbody Cages:** Placed between vertebrae after discectomy or corpectomy to maintain disc height, restore alignment, and promote bone fusion.
- **Posterior Cervical Screws and Rod Systems**: Provide strong posterior stabilization in trauma, deformity correction, instability, or failed previous fusion.
- **Artificial Cervical Disc (Disc Replacement Implant)**: Motion-preserving implant used in selected degenerative disc disease cases instead of fusion.
- **Expandable Cages / Vertebral Body Replacement Devices**: Used mainly after corpectomy for tumors, fractures, or severe vertebral body damage.

7. Suggested profile and training for users.

Specific training, including onsite demonstrations led by a product specialist are offered to ensure understanding of the product's functionality. Additionally, the DIAS platform for surgeons is available, focusing specifically on the surgical treatment of trauma spine, and musculoskeletal disorders offered by the Auxein. If further information on this product is needed, can visit https://www.auxein.com to review the product specific surgical technique for the system, Instruction for use, catalog available online.

8. Reference to any harmonized standards and CS applied.

The following harmonized standards and guidance documents are applicable on Cervical plating System:

Harmonized Standards		
S. No.	**Standard Designation**	**Title of Standard**
1.	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
2.	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
3.	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021).
4.	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
5.	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
6.	EN ISO 11607-1:2020/A1:2023	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
7.	EN ISO 11607-2:2020/A1:2023	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
8.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.
9.	EN ISO 11737-1:2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
10.	EN ISO 11737-2:2020	Sterilization of health care products -Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
11.	EN ISO 10993-18:2020/A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device

		materials within a risk management process (ISO 10993-18:2020).
12.	EN ISO 11137-1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)
13.	EN ISO 11137-2:2015/A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
14.	EN ISO 17665:2024	Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)
15.	EN ISO 14155:2020/A11:2024	Clinical investigation of medical devices for human subjects - Good clinical practice
16.	EN ISO 14630:2024	Non-active surgical implants - General Requirements

Non Harmonized Standards	
Standard	**Description**
ISO 20417:2026	Medical devices — Information to be supplied by the manufacturer
IEC 62366-1:2015/Amd 1:2020	Medical devices - Application of usability engineering to medical devices
ISO 14602:2010	Non-active surgical implants - Implants for osteosynthesis - Particular Requirements.
ISO 14644-1:2015	Clean-rooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.
ISO 14644-2:2015	Clean-rooms and associated controlled environments - Part 2: Monitoring to provide evidence of clean-room performance related to air cleanliness by particle concentration.
ISO 14644-3:2019	Clean-rooms and associated controlled environments - Part 3: Test Methods.
ISO 14644-4:2022	Clean-rooms and associated controlled environments - Part 4: Design, construction and start-up.
ISO 14644-5:2025	Clean-rooms and associated controlled environments - Part 5: Operations

ISO 14644-7:2004	Clean-rooms and associated controlled environments - Part 7: Separative devices (clean air hoods, glove boxes, Isolators and mini).
ISO 14644-8 :2022	Clean-rooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration (ACC).
ISO 14644-9 :2022	Clean-rooms and associated controlled environments – Part 9: Classification of surface cleanliness by particle concentration.
ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 5832-3:2021	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2021)
ISO 10993-1:2025	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-2: 2022	Biological evaluation of medical devices — Part 2: Animal welfare requirements
ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2026	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
ASTM F136-13 (2021)e1	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
ASTM D4169-22	Standard Practice for Performance Testing of Shipping containers and System.
ASTM F1717-21	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
ASTM 1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices.
ASTM F88/F88M-21	Standard Test Method for Seal Strength of Flexible Barrier Materials
ISO 19227:2018	Implants for surgery - Cleanliness of orthopedic implants - General requirements
ISO/TR 10993-33:2015	Biological evaluation of medical devices — Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3.

MDCG Guideline	
Guidance Documents	**Description**
MDCG 2021-24	Guidance on classification of medical devices
MDCG 2020-13	Clinical Evaluation Assessment Report Template
MDCG 2020-8	Guidance on PMCF evaluation report template
MDCG 2020-7	Guidance on PMCF plan template
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
MDCG 2020-5	Guidance on clinical evaluation – Equivalence
MDCG 2019-9, Rev.01	Summary of safety and clinical performance
MDCG 2019-5	Registration of legacy devices in EUDAMED
MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)
MDCG 2018-2	Future EU medical device nomenclature - Description of requirements
MDCG 2021-11	Guidance on Implant Card –'Device types'
MDCG 2022-16	Guidance on Authorized Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746
MDCG 2022-9	Summary of safety and performance template
MDCG 2019-14	Explanatory note on MDR codes
MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system
MDCG 2018-1, Rev.04	Guidance on BASIC UDI-DI and changes to UDI-DI
MDCG 2021-25	Application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 - December 2022
MEDDEV 2.7/1 revision 4, 2016	Clinical Evaluation: A guide for manufacturers and notified bodies.

9. Revision history

SSCP Revision Number	Date Issued	Change Description	Revision Validated by the Notified Body

00	23-10-2024	Initial Release	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
01	14-05-2026	Basic UDI-DI, Format and clinical data Updated	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
02	30-05-2026	Updated patient section as per LOF	☐ Yes Validation language: ☐ No ☐ (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

A summary of the safety and clinical performance of the device, intended for patients, is given below:
Document revision: 02
Date issued: 30-05-2026

Device identification and general information
Device Trade Name: Cervical Plate System
Manufacturer Name: Auxein Medical Private Limited
Manufacturer Address: Plot No. 168-169-170, Phase-IV, Sector-57, Kundli, HSIIDC, Industrial Area, Sonipat, Haryana 131028, India

Basic UDI-DI:	**Titanium Non-Sterile**	**Titanium Sterile**
Asterius-3.5mm Cancellous Screw, Self-Tapping, (Cross Head), Titanium	08903993008CPS001THT	08903993008CPS001TSVC
Asterius-4.0mm Cancellous Screw, Self-Tapping, (Cross Head), Titanium	08903993008CPS002THW	08903993008CPS002TSVH
Asterius-3.5mm Cancellous Screw, Self-Drilling, (Cross Head), Titanium	08903993008CPS003THZ	08903993008CPS003TSVN
Asterius-4.0mm Cancellous Screw, Self-Drilling, (Cross Head), Titanium	08903993008CPS004TJ4	08903993008CPS004TSVT
Asterius-3.5mm Cancellous Screw, Self-Tapping, (Hex Head), Titanium	08903993008CPS005TJ7	08903993008CPS005TSVY
Asterius-4.0mm Cancellous Screw, Self-Tapping, (Hex Head), Titanium	08903993008CPS006TJA	08903993008CPS006TSW5
Asterius-3.5mm Cancellous Screw, Self-Drilling, (Hex Head), Titanium	08903993008CPS007TJD	08903993008CPS007TSWA
Asterius-4.0mm Cancellous Screw, Self-Drilling, (Hex Head), Titanium	08903993008CPS008TJG	08903993008CPS008TSWF
REGEX-Anterior Cervical Plate, Level-I, Titanium	08903993008CPS009TJK	08903993008CPS009TSWL
REGEX-Anterior Cervical Plate, Level-II, Titanium	08903993008CPS010THV	08903993008CPS010TSVE
REGEX-Anterior Cervical Plate, Level-III, Titanium	08903993008CPS011THY	08903993008CPS011TSVK
REGEX-Anterior Cervical Plate, Level-IV, Titanium	08903993008CPS012TJ3	08903993008CPS012TSVQ
4.0mm REGEX-Bone Screw, Self-Drilling, Variable Angled, Titanium	08903993008CPS013TJ6	08903993008CPS013TSVV
4.0mm REGEX-Bone Screw, Self-Drilling, Fixed Angled, Titanium	08903993008CPS014TJ9	08903993008CPS014TSW2

4.5mm REGEX-Bone Screw, Self-Drilling, Variable Angled, Titanium	08903993008CPS015TJC	08903993008CPS015TSW7
4.5mm REGEX-Bone Screw, Self-Drilling, Fixed Angled, Titanium	08903993008CPS016TJF	08903993008CPS016TSWC
4.0mm REGEX-Bone Screw, Self-Tapping, Variable Angled, Titanium	08903993008CPS017TJJ	08903993008CPS017TSWH
4.0mm REGEX-Bone Screw, Self-Tapping, Fixed Angled, Titanium	08903993008CPS018TJM	08903993008CPS018TSWN
4.5mm REGEX-Bone Screw, Self-Tapping, Variable Angled, Titanium	08903993008CPS019TJQ	08903993008CPS019TSWT
4.5mm REGEX-Bone Screw, Self-Tapping, Fixed Angled, Titanium	08903993008CPS020TJ2	08903993008CPS020TSVM
Asterius-Anterior cervical Plate	08903993008CPS021TJ5	08903993008CPS021TSVS

Year when the device was first CE-marked: 2014

Intended use of the device

Intended Purpose	The Cervical Plate System is intended for anterior inter-body screw fixation of the cervical spine during the development of a cervical spinal fusion.
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.
Intended Patient Population	Skeletelly mature male and female Subjects aged between 18-75 years.

Device description

The Cervical Plate System is a group of medical implants used to support and stabilize the neck portion of the spine (cervical spine). These implants may be used in patients who have spinal problems such as wear-and-tear of the spinal discs (degenerative disc disease), narrowing of the spinal canal (spinal stenosis), spinal deformities, or fractures (broken bones) in the neck.

The devices help keep the bones in the correct position, provide support to the spine, and assist the bones in healing and fusing together after surgery.

All devices in the Cervical Plate System are made from a strong, lightweight titanium alloy that is commonly used in medical implants because it is durable and compatible with the human body.

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

The Asterius-Anterior Cervical Plate is an implant used during neck (cervical spine) surgery to help stabilize and support the spine while the bones heal and fuse together. The plate is attached to the bones of the spine using screws to hold them in the correct position.

2. **Regex Anterior Cervical Plate System, Titanium**

The REGEX Anterior Cervical Plate System is a medical implant used during neck (cervical spine) surgery to help stabilize and support the spine while it heals. It can be used when one or several bones in the neck need to be treated.

Manufacturer's SRN	IN-MF-000018837		
Parameter	Details	Certified By	Certificate Number
Legacy Device	Yes, Cervical Plate System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	10000363901-PA-NA-IND Rev. 3
Year when the first certificate (CE) was issued covering the device	2014		
EMDN Code	P09070301		
Conformity Assessment Route	Conformity Assessment of Class IIb devices has been conducted as per Article 52 (4), Chapter I, II and III of Annex IX of EU MDR 2017/745		
Raw Materials of Implants	The Raw Materials used for manufacturing the Implants consists of Titanium alloy Ti-6AL-4V as per ISO 5832-3:2021.		
USFDA Approved	Not Applicable		
Risk Class	IIb {According to REGULATION (EU) 2017/745 (MDR) OF THE EUROPEAN PARLIAMENT, Annex VIII,Chapter-3, Rule 8.		
Authorized Representative Name and Address	Name: CMC Medical Devices & Drug S.L Address: 29015 Málaga, Spain		
Authorized Representative SRN	ES-AR-000000293		
Notified Body Name and Single Identification Number	Name: DNV Product Assurance AS Single Identification Number: 2460		

Principle of operation

Cervical Plate System works on the AO Principle of Fracture Management. The key concept of fracture management involves:

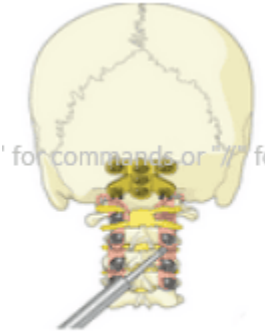
1. Stability
2. Alignment

3. Function
4. Biology

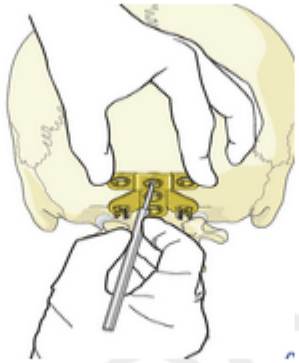
The Auxein's Cervical Plate System aims for stabilization of the cervical bone anatomy by balancing the spine in three dimensions which helps preservation and restorations of function to prevent disability. The proper fixation of the plate preserves the biology that provides better tissue healing and neural protection by following surgical technique provided by the manufacturer.

Scientifically demonstration of Principle of Operation

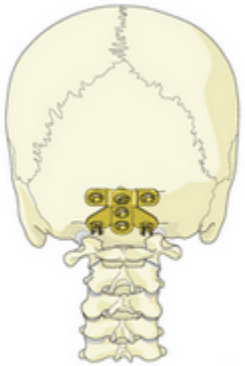
Step 1: Angular stability



Step 2: Rotational stability



Step 3: Longitudinal Stability



Description of Key functional elements:

The Cervical Plate System comprises of functional elements as :

- Screws

The description of the functional element used with Plate to fix the fracture enlisted below.

Screw

- It is intended to be used for the implantation of any type of internal Orthopedic Fixation System.
- It is used for internal orthopaedic fracture fixation by being screwed into bone to hold Plate with cervical bone.
- In the Cervical Plate System various types of screws are included like cancellous screw (self tapping & self drilling), Regex bone screw (variable angled screw and fixed angled screw).

Risks and Warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

The potential risks that arise regarding the device are controlled using risk mitigation method and conveying those risk to the patients from surgeon.

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

Warning & 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 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.

Summary of any field safety corrective action, (FSCA including FSN) if applicable
Till now, regarding Auxein's Cervical Plate System there is no FSCA.

Summary of clinical evaluation and post-market clinical follow-up
Clinical background of the device:
Description and consequences
The cervical spine is the part of the spine located in the neck. It is made up of seven bones, called vertebrae, which are numbered C1 to C7. These bones support the head, protect the spinal cord, and allow the neck to move in different directions, such as bending, turning, and looking up or down.

- **C1 (Atlas):** Supports the skull and helps you nod your head.
- **C2 (Axis):** Helps you turn your head from side to side.
- **C3 to C7:** Support the neck and allow normal neck movements while protecting the spinal cord and nerves.

Types of Cervical Fractures:

- **Compression fractures**: These occur when the vertebra is crushed or compressed.
- **Dislocations**: The vertebrae are displaced from their normal alignment.
- **Fracture-dislocations**: A combination of both a fracture and a dislocation, which is often more severe.
- **Hangman's fracture**: A type of fracture involving the C2 vertebra, often resulting from sudden hyperextension of the neck.

Types of Cervical Deformities

- **Cervical Kyphosis:** The neck curves forward more than normal, which can cause pain, difficulty holding the head upright, and nerve-related symptoms.
- **Cervical Scoliosis:** The neck curves sideways and may also twist, leading to uneven posture and discomfort.
- **Loss of Cervical Lordosis:** The normal inward curve of the neck becomes straight or reverses, which may cause neck pain, stiffness, and muscle strain.

Causes of cervical fracture:

Cervical fractures can occur for several reasons, including:

- Road traffic accidents, especially high-speed collisions.
- Sports injuries, particularly in contact sports or activities with a risk of falls.
- Falls from a height or falls in older adults.
- Workplace accidents involving heavy equipment or hazardous environments.
- Osteoporosis, a condition that weakens bones and makes them more likely to break.
- Physical violence or severe trauma to the neck.
- Tumors, infections, or other diseases that weaken the bones of the spine.
- Conditions present from birth that affect spinal stability.
- Age-related wear and tear, such as arthritis or degenerative disc disease.
- Severe neck bending, twisting, or compression injuries.
- Repeated strain or stress on the neck over a long period.

Symptoms

1. Pain
2. Stiffness
3. Headache
4. Numbness
5. Loss of coordination

6. Breathing difficulties
7. Difficulty Swallowing or speaking

Complications

1. Nerve or spinal cord damage
2. Paralysis
3. Pseudarthrosis
4. Malunion
5. Neurological issues such as sensory deficits and Motor impairment
6. Posoperative infection

Diagnosis

To diagnose a fracture or other problem in the cervical spine, your doctor will first ask about your symptoms and perform a physical examination. The doctor may gently examine your neck and back to identify areas that are painful or tender and check for any changes in your posture, neck movement, or the shape of your spine.

To confirm the diagnosis and understand the extent of the injury, your doctor may recommend one or more imaging tests:

- **X-ray:** An X-ray can show whether a bone in the neck is broken and whether the bones are still in their normal position.
- **MRI (Magnetic Resonance Imaging):** An MRI provides detailed images of the spinal cord, nerves, discs, and other soft tissues around the spine. This helps the doctor determine whether the injury is affecting the spinal cord or nearby nerves.
- **CT (Computed Tomography) Scan:** A CT scan provides detailed images of the bones and is often used when surgery is being considered. It helps the surgeon understand the exact location and severity of the injury.

Pain Management

After surgery, it is normal to experience some pain and discomfort while the body heals. Pain is usually managed with medications prescribed by your doctor. These may include pain-relieving medicines and, in some cases, medicines to reduce muscle spasms or nerve-related pain.

Some patients may be advised to wear a neck collar for a short period to support the neck during healing. Gentle physical therapy and guided exercises may also help reduce pain, improve comfort, and support recovery while protecting the spine.

Rehabilitation and Return to Activity

Recovery after cervical spine surgery focuses on allowing the bones to heal properly while helping you gradually return to your normal activities.

In the first few weeks after surgery, your doctor may recommend:

- Wearing a neck collar if needed.
- Taking care of the surgical wound as instructed.
- Walking and moving around as advised to support recovery.
- Performing gentle shoulder and arm exercises to prevent stiffness.
- Avoiding heavy lifting, sudden neck movements, and strenuous activities.

As healing progresses and follow-up X-rays or scans show that the spine is stable, a structured rehabilitation program may begin. This may include:

- Gentle neck movement exercises.
- Exercises to improve strength and posture.
- Activities to improve balance, coordination, and overall function.

Most patients can gradually return to normal daily activities under their doctor's guidance. Returning to physically demanding work, heavy lifting, or sports should only occur after the spine has healed adequately and your surgeon confirms that it is safe to do so.

Clinical Evidence/Safety of the device:

Prospective Clinical Evaluation:

Prospective Study of the legacy device has been approved by the ethics committee.

Prospective Clinical Data (PMCF Study):

Prospective Study of the legacy device has been approved by the ethics committee.

Identity of the investigation/study: A Prospective, Single Arm, Post Market Clinical Follow- up (PMCF) study to evaluate the Safety and Performance of Cervical System.

Name or Code of Study	Completed (Yes/No)	Name of countries in study is conducted	No. of patients enrolled/and the target no.	No. of serious incidents	Serious incident rate (%)	No. of deaths
	Ongoing	**INDIA**	**16/30**	**0**	**0**	**0**

Study Title	A Prospective, Single Arm, Post Market Clinical Follow- up (PMCF) study to evaluate the Safety and Performance of Cervical System.	
CTRI Number	CTRI/2024/10/074836	
CTRI Registration Date	07/10/2024	
Number of study sites	2	
Name of Study Sites	Stavya Spine Hospital and Research Institute, Ahmedabad.	Maulana Azad Medical College & Associated Lok Nayak Hospital
No. of Patients enrolled	16	

Study design: A Prospective, Single Arm, Post Market Clinical Follow-up (PMCF) study to evaluate the Safety and Performance of Cervical System. This longitudinal study was designed as a single-arm study. The target population for this research comprised both males and females aged 18 years or older at the time of surgery. The study aimed to recruit a total of 60 subjects due for cervical surgery viz. deformity correction, stabilize and strengthen the cervical spine region in patients suffering from degenerative disc disease, damaged or unstable vertebral body and fractures.

Inclusion criteria

1. Patients presenting to Orthopaedic OPD/emergency, requiring treatment with anterior cervical plate or/and cage.
2. Male and female, aged between 18- 75 years

Exclusion criteria

1. Patients with active local or systemic infection.
2. Patients with morbid obesity (BMI >35 kg/m2)
3. Patients with mental disorders or currently on psychiatric treatment.
4. Alcoholics and or drug abusers.
5. Patients with metabolic bone disease.
6. Severe osteopenia
7. Metal sensitivity/allergies
8. Pregnant women or those planning pregnancy during study.

Primary Objective

1. 1. To assess performance of cervical system by radiological evaluation.
2. To evaluate the improvement in pain through Visual Analogue Scale (VAS).

Secondary Objective

1. 1. To assess the improvement in quality of life through Neck disability index (NDI).
2. To record and analyze complications including serious adverse events.

Primary Endpoints

1. Radiological evaluation by X-rays will be done to assess the performance of implants at each post-operative follow up visit (6 week, 6 Month, and 12 Month).
2. To evaluate improvement in pain, VAS score will be recorded at each post-operative follow up visit (6 week, 6 Month, and 12 Month).

Secondary Endpoints

1. To evaluate improvement in quality of life, NDI will be recorded at each post- operative follow up visit (6 week, 6 Month, and 12 Month).
2. To ascertain the safety of implants, post-operative complications including serious adverse events will be recorded at each follow up visit (6 week , 6 Months, and 12 Months).

6. **Possible diagnostic or therapeutic alternatives.**

Initial evaluation of the cervical fracture include a range of imaging and management strategies selected according to fracture characteristics, stability, neurological status, and patient-specific factors. Diagnostic evaluation commonly begins with plain radiographs (anteroposterior, lateral, and open-mouth odontoid views), while computed tomography (CT) is the preferred modality for detailed assessment of fracture pattern, alignment, and stability. Magnetic resonance imaging (MRI) is an important adjunct for evaluating spinal cord injury, ligamentous disruption, intervertebral disc involvement, and occult fractures not clearly visualized on radiographs or CT, and in selected neurologically intact patients, dynamic flexion–extension radiographs may be used in the subacute phase to assess residual instability. Therapeutic alternatives range from non-surgical management, including immobilization with a rigid cervical collar, cervicothoracic orthosis, or halo vest for stable fractures without neurological deficit, to surgical management for unstable fractures, progressive deformity, neurological impairment, or failure of conservative treatment. Surgical options include anterior approaches (such as anterior cervical plating or corpectomy with fusion), posterior stabilization (including lateral mass or pedicle screw fixation), or combined anterior–posterior techniques, chosen based on fracture morphology and stability requirements, with the goals of achieving stable fixation, decompression when indicated, correction of deformity, and early

mobilization.

Treatment

Anterior cervical plates are primarily used to provide anterior stabilization and promote fusion. However, several conservative and surgical alternatives exist depending on spinal stability, neurological status, number of levels involved, and patient-specific factors.

1. Conservative (Non-Surgical) Treatment

For stable fractures that do not involve the spinal cord or significant misalignment, non-surgical treatment is typically sufficient.

A. Immobilization:

- **Cervical Collar or Brace:** A neck brace or cervical collar (like a Philadelphia collar) is often used to keep the neck stable and restrict movement, allowing the fracture to heal. The duration of use varies depending on the severity of the fracture but can range from several weeks to months.

- **Halos:** In some cases, a halo vest may be used. This involves a metal ring (halo) attached to the skull with pins, which is then connected to a chest vest. This provides more rigid immobilization and is typically used in more severe fractures when the risk of spinal cord injury is higher.

B. Pain Management:

- Over-the-counter pain relievers like acetaminophen or NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) are typically prescribed for pain control.
- Muscle relaxants may also be given to reduce muscle spasms in the neck.
- Opioid pain medications might be prescribed for short-term use in more severe pain cases, though these are used with caution due to the potential for addiction or side effects.

C. Physical Therapy:

- Once the acute phase of the injury has passed, physical therapy may be initiated to help improve neck mobility, strengthen muscles, and reduce stiffness.
- This will typically begin with gentle range-of-motion exercises and progress as healing occurs.

D. Monitoring:

- Regular follow-up visits with the doctor to monitor healing through X-rays or CT scans are common to ensure proper alignment and that the fracture

is healing as expected.

2. Surgical Treatment

Surgical treatment options for cervical spine indications depend on the pathology, severity of symptoms, neurological involvement, spinal stability, and patient health status. Below are commonly used surgical options for the listed cervical conditions:

- **Cervical Plate and Screws:** Used in anterior cervical fusion procedures to provide immediate stability and maintain alignment after disc or vertebral body removal.
- **Interbody Cages:** Placed between vertebrae after discectomy or corpectomy to maintain disc height, restore alignment, and promote bone fusion.
- **Posterior Cervical Screws and Rod Systems**: Provide strong posterior stabilization in trauma, deformity correction, instability, or failed previous fusion.
- **Artificial Cervical Disc (Disc Replacement Implant)**: Motion-preserving implant used in selected degenerative disc disease cases instead of fusion.
- **Expandable Cages / Vertebral Body Replacement Devices**: Used mainly after corpectomy for tumors, fractures, or severe vertebral body damage.

Suggested training for users

Specific training, including onsite demonstrations led by a product specialist are offered to ensure understanding of the product's functionality. Additionally, the DIAS platform for surgeons is available, focusing specifically on the surgical treatment of trauma spine, and musculoskeletal disorders offered by the Auxein. If further information on this product is needed, can visit https://www.auxein.com to review the product specific surgical technique for the system, Instruction for use, catalog available online.