SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR SPINAL SCREWS SYSTEM

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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: 08903993SS007N5

SRN: IN-MF-000018837

The Spinal Screw System includes the following as listed below:

VERTAUX 5.5mm Pedicle Screws System

a. VERTAUX - Monoaxial Pedicle Screw with Cap
b. VERTAUX - Monoaxial Reduction Pedicle Screw with Cap
c. VERTAUX - Polyaxial Pedicle Screw with Cap
d. VERTAUX - Polyaxial Reduction Pedicle Screw with Cap
e. VERTAUX - Pedicle Screw Cap, M9
f. VERTAUX - Cross Link- I
g. VERTAUX - Cross Link- II
h. VERTAUX Crosslink Connector Type-III
i. VERTAUX – Rod
j. Pedicle Hook
k. Laminar Hook
l. VERTAUX - Multiaxial Iliac Screw with Cap
m. VERTAUX - Multiaxial Iliac Screw, Offset Connector
n. VERTAUX - Multiaxial Iliac Screw, Offset Connector

Osteobone Dual Threaded Screw

a. OSTEOBONE Multiaxial Pedicle Fenestrated Dual Thread Screw

b. OSTEOBONE - Pedicle Screw Cap, M9

VERTAUX Occipital System

a. VERTAUX - Occipital Polyaxial Pedicle Screw
b. VERTAUX - Occipital Polyaxial Pedicle Screw, Partial Thread
c. VERTAUX - Occipital Inner Screw Cap (M6)
d. VERTAUX - Occipital Pre Bent Rod
e. VERTAUX - Occipital Laminar Hook
f. VERTAUX - Occipital Straight Rod
g. VERTAUX - Occipital Crosslink
h. VERTAUX - Occipital Lateral Offset Connector
i. VERTAUX - Occipital Plate
j. VERTAUX - Occipital Pre Bent Rod for Plate
k. VERTAUX - Occipital Screw
l. Universal Connector

VERTAUX Basico Polyaxial Screw

a. VERTAUX Basico Polyaxial Screw with Cap
b. VERTAUX Basico Polyaxial Conical TH Screw with Cap
c. VERTAUX Basico Polyaxial Screw Rod
d. VERTAUX - Pedicle Screws Cap M9

VERTAUX MIS Screw System

a. VERTAUX MIS Polyaxial Screw with Cap
b. VERTAUX MIS Monoaxial Screw with Cap
c. VERTAUX MIS Pre Bend Rod

d. VERTAUX MIS Straight

e. VERTAUX MIS Inner Screw Cap

Details Regarding the device are provided in below table:

Device Trade Name:	**Spinal Screw 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		
Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, Spinal Screw System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	10000363901-PA-NA-IND Rev 2
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 EN ISO 5832-3:2021.		
USFDA Cleared	Yes (Spinal Screws System are cleared by USFDA whose details are as follow:) **510(k) Number:** K201457		
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 Spinal screw intended to be placed in spinal bone to treat fracture 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 Spinal screw comes in contact with the spinal 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 Spinal screw 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 Spinal screw 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 case they are classified as class III;

Applicable/ Not Applicable: Not Applicable

Justification: The Spinal screw implants made up of metal alloys to provide support for the fractured spinal bone. The system is not intended to administer medicinal products.

6. Are active implantable devices or their accessories, in which cases 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 Spinal screw system does not depend on a source of energy. 7. Are breast implants or surgical meshes, in which cases they are classified as class III; *Applicable/Not Applicable*: Not Applicable *Justification*: The Spinal screw system treats spine bone fracture. 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 Spinal screw system treats spine bone fracture. Not intended for Total or Partial Joint Replacements. 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*: Not Applicable *Justification*: The Spinal screw system is an implantable device that comes in contact with the spinal column, but it is a screw therefore this section is not applicable.
Authorized Representative Name and Address	**Name:** CMC Medical Devices & Drug S.L **Address:** 29015 Málaga, Spain
Authorized Representative SRN	ES-AR-00000029
Notified Body Name and Single Identification Number	**Name:** DNV Product Assurance AS **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	**VERTAUX 5.5mm Pedicle Screw System** The VERTAUX 5.5mm Pedicle Screw System is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor and pseudarthrosis. **VERTAUX Occipital System** The VERTAUX Occipital System is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor and pseudarthrosis. **VERTAUX Basico Polyaxial Screw** The VERTAUX Basico Polyaxial Screw System is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor and pseudarthrosis. **VERTAUX MIS Screw System** The VERTAUX MIS Screw System is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor and pseudarthrosis.

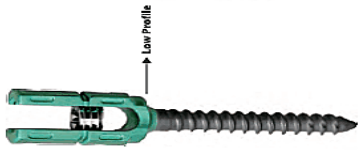
	Osteobone Dual Threaded Screw The Osteobone Dual Threaded Screw is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor and pseudarthrosis.
Contraindications	Contraindications may be relative or absolute. The conditions listed below may preclude or reduce the chance of a successful outcome: ○ Active infectious process or significant risk of infection (immuno compromise). ○ Signs of local inflammation. ○ Fever or leukocytosis. ○ Morbid obesity. ○ Pregnancy. ○ Mental illness. ○ Grossly distorted anatomy caused by congenital abnormalities. ○ Suspected or documented metal allergy or intolerance. ○ Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality. ○ Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance. ○ Any patient unwilling to follow postoperative instructions. ○ Any case not described in the indications.
Intended Patient Population	Skeletally mature Male and female patients aged 18 years to 60 Years.
Intended Users	The Spinal screw 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 Spinal Screw System are Bio-compatible. Biocompatibility of the devices is tested as per EN ISO 10993-1:2020 series of International Standard.

3. Description of the device

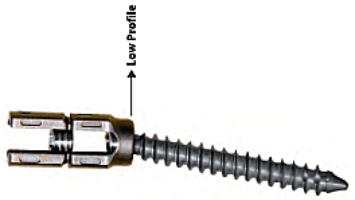
1.	Vertaux 5.5 mm Pedicle Screw System	
a.	Vertaux-Monoaxial Pedicle Screw with Cap	
	Picture	
	Total Length	25mm-55 mm (Increment of 5mm)
	Diameter	4.5mm-7.0mm (Increment of 5mm)
	Head Width	12.6 mm
	Head Length	12.36 mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

b.	Vertaux-Monoaxial Reduction Pedicle Screw with Cap

	Picture	
	Total Length	25mm-55mm (Increment of 5mm)
	Diameter	4.5mm-7.0 mm (Increment of 5mm)
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

c.	Vertaux-Polyaxial Pedicle Screw with Cap	
	Picture	
	Total Length	25mm-5mm (Increment of 5mm)
	Diameter	4.5mm-7.0 mm (Increment of 5mm)
	Head Width	7.10 mm
	Head Length	4.40 mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

d.	Vertaux-Polyaxial Reduction Pedicle Screw with Cap

	Picture	
	Total Length	25mm-55 mm (Increment of 5mm)
	Diameter	4.5mm-7.0 mm (Increment of 5mm)
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

e.	Vertaux-Pedicle Screw Cap, M9	
	Picture	
	Diameter	9mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

f.	Vertaux-Cross Link-I

	Picture	
	Total Length	50, 55, 60 mm
	Width	8.40mm
	Hook Radius	5.55mm
	Rod Diameter	4.0mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

g.	Vertaux-Cross Link-II	
	Picture	
	Total Length	40mm to 120mm
	Rod Width	4.0mm
	Connector Width	11.0mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

h.	Vertaux-Cross Link Connector Type III

	Picture	
	Total Length	36-39, 39-45, 45-57, 58-81 mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

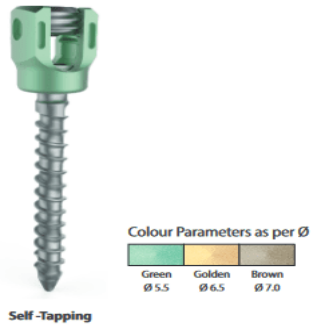
i.	Vertaux-Rod	
	Picture	
	Total Length	50mm to 500mm
	Diameter	5.5 mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

j.	Pedicle Hook

	Picture	
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

k.	Laminar Hook	
	Picture	
	Narrow	5.0mm-9.5mm (Increment of 5mm)
	Wide	5.0mm-9.5mm (Increment of 1.5mm)
	Angle	Left/Right
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

l.	VERTAUX - Multiaxial Iliac Screw

	Picture	
	Diameter	5.5mm, 6.5mm, 7.0mm
	Length	65mm-110mm (Increment 5mm)
	Angle	Left/Right
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

m.	VERTAUX - Multiaxial Iliac Screw, Offset Connector	
	Picture	
	Narrow	5.0mm-9.5mm (Increment of 1.5mm)
	Wide	5.0, 6.5, 8.0 and 9.5mm
	Angle	Left/Right
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

n.	VERTAUX - Multiaxial Iliac Screw, Offset Connector, Nut	
	Picture	
	Narrow	5.0mm-9.5mm (Increment of 1.5mm)
	Wide	5.0mm-9.5mm (Increment of 1.5mm)
	Angle	Left/Right
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

2.	OSTEOBONE DUAL THREAD SCREW	
a.	Device Name	Osteobone Multiaxial Pedicle Fenestrated Dual Thread Screw

	Image	
	Diameter	4.5mm-7.0mm (Increment of 0.5mm)
	Length	20mm-65mm (Increment of 5mm)
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

b.	Device Name	OSTEOBONE - Pedicle Screw Cap M9

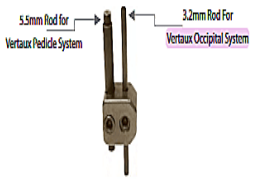
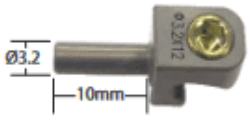
	Image	
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

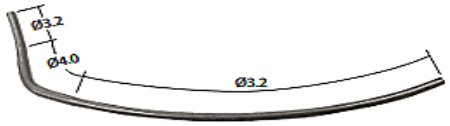
3.	Vertaux Occipital System	
a.	Device Name	VERTAUX - Occipital Polyaxial Pedicle Screw
	Picture	
	Diameter	3.5mm

	Length	5mm-14mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021
b.	Device Name	VERTAUX - Occipital Polyaxial Pedicle Screw, Partial Thread
	Picture	
	Diameter	4.0mm
	Length	5mm-14mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021
c.	Device Name	VERTAUX - Occipital Inner Screw Cap
	Picture	

	Product Specification	M6
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021
d.	Device Name	VERTAUX - Occipital Pre Bent Rod
	Picture	
	Dia	3.2mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021
e.	Device Name	VERTAUX - Occipital Laminar Hook
	Picture	
	Product Specification	Small & Large

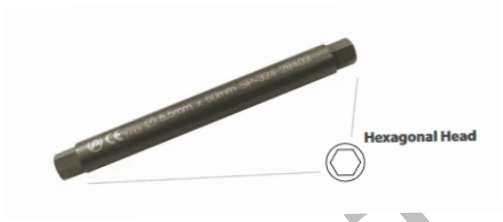
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021
f.	Device Name	VERTAUX - Occipital Straight Rod
	Picture	
	Diameter	3.2mm
	Length	70mm , 120mm, 200mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021
g.	Device Name	VERTAUX - Occipital Cross link
	Picture	
	Length	60mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

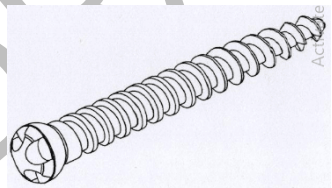
h.	Device Name	Universal Connector
	Picture	
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021
i.	Device Name	VERTAUX - Occipital Lateral Offset Connector
	Picture	
	Dia X Length	3.2mm x 12mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

j.	Device Name	VERTAUX - Occipital Plate
	Picture	
	Length	32mm, 37mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021
k.	Device Name	VERTAUX - Occipital Pre Bent Rod for Plate
	Picture	
	Diameter	3.2mm
	Length	160mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

l.	Device Name	VERTAUX - Occipital Screw
	Picture	
	Length	6mm-12mm (Increment of 2mm)
	Diameter	4.0mm, 4.5mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

4.	VERTAUX Basico Polyaxial Screw	
a.	Device Name	Vertaux Basico Polyaxial Screw with Cap
	Image	
	Diameter	4.5mm-7.0mm (Increment of 0.5mm)
	Length (mm)	25mm-55mm (Increment of 5mm)
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

b.	Device Name	Vertaux Basico Polyaxial Screw Rod
	Image	
	Length (mm)	400mm
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

c.	Device Name	Vertaux Basico Polyaxial Conical TH Screw with Cap
	Image	
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

d.	Device Name	VERTAUX - Pedicle Screws Cap, M9

	Image	 
	Product Specification	M9
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

5.	VERTAUX MIS Screw	
a.	Device Name	VERTAUX MIS Polyaxial Screw with Cap
	Image	
	Diameter	5mm-7mm (Increment of 0.5mm)
	Length	30mm-60mm (Increment of 5mm)
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

b.	Device Name	VERTAUX MIS Inner Screw Cap
	Image	
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

c.	Device Name	Vertaux MIS Monoaxial Screw with Cap
	Image	
	Diameter	5mm-7mm (Increment of 0.5mm)
	Length	30mm-60mm (Increment of 5mm)
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

d.	Device Name	Vertaux MIS Pre Bend Rod
	Image	
	Diameter	5.5 mm
	Length	30mm-500mm (Increment of 5mm)
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

e.	Device Name	Vertaux MIS Straight

	Image	
	Diameter	5.5 mm
	Length	30mm-500mm (Increment of 5mm)
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021

A Detailed device description is given in below table.

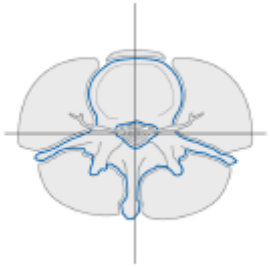
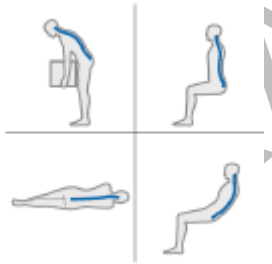
Other details of the Spinal Screw System:

Device Compliance to regulation		We are proposing the Spinal Screw 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	Auxein Spinal Screw System
	General Description	The AUXEIN MEDICAL'S Spinal Screws consists of a variety of shapes and sizes of screws. However,

		all the screws of the Spinal Screws System are broadly classified into the 5 different categories: a. VERTAUX 5.5mm Pedicle Screw System b. VERTAUX Osteobone Dual Threaded Screw c. VERTAUX Occipital System d. VERTAUX Basico Polyaxial Screw e. VERTAUX MIS Screw System
	Intended Purpose	The Spinal screw system is intended to maintain the anatomical integrity of the spine by adding extra support and strength to the fusion while it heals.
	Intended Users	The Spinal screw system is recommended to be used by only well-trained, certified and experienced surgeons
b.	Intended Patient Population	Skeletally mature Male and female patients aged 18 years to 60 Years.
	Medical Conditions to be diagnosed, treated and/or monitored	The Spinal Screw System is used to treat abnormality of spinal column.
	Patient Selection Criteria	Patient Inclusion Criteria: Male and female subjects aged 18 years to 60 Years. Exclusion Criteria: Subjects with pedicle deformity were not eligible for participation in the study. Additionally, subjects with the history Neurofibromatosis type 2 were excluded. Those with metabolic disorder that could pose a high risk of fixation failure or complications in postoperative care, any other condition that could hinder the potential benefits of implant insertion surgery and disrupt the normal process of bone remodeling (e.g., the presence of tumors or congenital abnormalities, fractures local to the operating site), elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell (WBC) count, or a marked left shift in the WBC differential count were also excluded. Moreover, subjects with suspected or

		documented allergy or intolerance to implant materials were not included in the study. Surgeons were required to identify any allergic reactions to the material of the implant (information on the implant material is provided in the IMPLANT MATERIAL section) and exclude such subjects from the study.
c.	Principles of Operation	Spinal Screw System works on the AO Principle. The key concept involves: 1. Stability: Stabilization to achieve a specific therapeutic outcome 2. Alignment: Balancing the spine in three dimensions 3. Biology: Etiology, pathogenesis, neural protection, and tissue healing 4. Function: Preservation and restoration of function to prevent disability
	Mode of Action	The pedicle screw fixation devices allow the fusion of fewer motion segments in the treatment of spinal fractures compared to non-pedicular fixation system. Pedicle screw fixation system has been currently used in the surgical treatment of spinal deformities.

	Scientifically demonstration of Principle of Operation	Step 1: Stability  Step 2: Alignment  Step 3: Biology

		 Step 4: Function 
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, Spinal screw system is an implant used in humans for medical purposes to treat spinal diability..* **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 Spinal screw system is an implant used for the treatment of spinal bone fracture. 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 Spinal screw is an implantable device used for the treatment of spinal bone fractures. c) investigation,replacement or modification of the anatomy or of a physiological or pathological processor state- **Not Applicable** ***Rationale for Non Applicability*** The Spinal screw is intended to treat spinal bone fracture in order to maintain its anatomical state. The screw 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***

		Spinal screw is made up of metal alloy and employed to fix spinal fractures. 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 spinal screw 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 Spinal screw system is used to stabilize spinal bone fracture. 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 Spinal screw system is intended for fixation for fractures of the spinal bone. The system is not meant for cleaning, disinfection or sterilization of device.
e.	Novel Features	The Spinal Screw 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	**Screw** The pedicle screw is a screw that is generally used treat the different types of spinal disorder like scoliosis, kyphosis. The screw is used around the pedicle region of vertebra. It has a unique shaped head called tulip and it is used to hold the rod. In some screw tulip is statically fixed and in some case is rotated in around 15 degree in all axis and called as polyaxial screw. Some of the screw are mono threaded while some are dual threaded. **Rod** The rod is used to provide the stabilization of the vertebra. It is fixed in the tulip of the screw with the help of the end cap. **Hook** The hook is one of the small components of the spinal screw system with significant importance. It is used to anchor the vertebra with the rod. **Cross link** Cross link is used to connect the both rod used for the stabilization with each other and provides the additional stability to the screw by increasing the rotational stiffness. **End Cap** End cap is used to the fix the rod in the tulip and prevent from the back out. Similarly, it also fixes the hook with the rod.
g.		
	Sterility	All Products covered in Spinal Screw 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 Spinal Screw 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 Spinal Screw System are Bio-compatible. Biocompatibility of the devices is tested as per ISO 10993 series of International Standard.
	MRI Compatibility	The Spinal Screw 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 Spinal Screw 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 2
	USFDA Approved	Yes (Spinal Screw System are approved by USFDA whose details are as follow:) 510(k) Number: K201457

b.	Similar devices available in Union or international market.	The Similar devices available in the Union or International Market enlisted below: Matrix Spine System:Depuy Synthes (CE 0123) Polaris 5.5 Spinal System: Zimmer Biomet (CE 0086) Xia 3: Styker (CE 0123) CD Horizon® Legacy™ Spinal System: Medtronic

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

Residual risks and undesirable effects

A listing of potential adverse events includes, but is not limited to:

- Early or late loosening of any or all of the components.
- Disassembly, bending, or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, or general corrosion) including metallosis, staining, tumor formation, or autoimmune disease.
- Pressure on the skin from component in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, or pain.
- Bursitis.
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function (e.g. sensory or motor) including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, or visual deficits.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia paraparesis, reflex deficits, irritation, arachnoiditis, muscle

loss.

- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, or vertebral body) or bone graft or bone graft harvest site at, above, or below the level of surgery.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Non-union (or pseudarthrosis), delayed union, or mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Ileus, gastritis, bowel obstruction or loss of bowel control, or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Development of respiratory problems (e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.)
- Change in mental status.
- Death.

Warning & Precautions:

The safety and effectiveness of spinal Screw systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prostheses. In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend, or fracture as a result of exposure to every day mechanical stresses. A device that has been implanted should never be reprocessed or reused under any circumstances. Non-Sterile packaged devices should be sterilized

before use. Reprocessing or reuse may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death.

The implantation of Spinal screw systems should be performed only by experienced spinal surgeons with specific training in the use of this screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient. 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. No spinal implant can 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 and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

Safety and Performance Parameters:

- Measure the Oswestry Disability Index (ODI)
- Measure the VAS Score
- Record of any adverse event (rate of loosening of Pedicle Screw), serious adverse event and complication

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, multi-centric, post marketing clinical follow-up study to evaluate the safety and performance of pedicle screws in patient with spinal disorders.

Name or Code of Study	Completed	Name of countries in	No. of patients enrolled	No. of serious	Serious incident	No. of deaths

	(Yes/No)	study is conducted	/and the target no.	incidents	rate (%)	
CR_PMCF/P_01	Ongoing	INDIA	13/159	0	0	0
Study Title	A prospective single arm, multi-centric, post marketing clinical follow-up study to evaluate the safety and performance of pedicle screws in patient with spinal disorders.					
CTRI Number	CTRI/2023/03/051092					
CTRI Registration Date	27/03/2022					
Number of study sites	Two					
Name of Study Sites	a. Lok Nayak Hospital, New-Delhi, India and b. Stavya Spine Hospital & Research Institute Ellis Bridge, Gujarat, India					
No. of Patients enrolled	13					

Study design: The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the Pedicle Screw device. 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 159 subjects who met with Degenerative disc disease using Pedicle Screw device.

Inclusion criteria

Male and female subjects aged 18 years to 60 Years, who had pedicle placement surgery and were willing to attend all study visits, were recruited for this study. Prior to enrollment, written informed consent for participation was obtained from all the study subjects.

Exclusion criteria

Subjects with pedicle deformity were not eligible for participation in the study. Additionally, subjects with the history Neurofibromatosis type 2 were excluded. Those with metabolic disorder that could pose a high risk of fixation failure or complications in postoperative care, any other condition that could hinder the potential benefits of implant insertion surgery and disrupt the normal process of bone remodeling (e.g., the presence of tumors or congenital abnormalities, fractures local to the operating site), elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell (WBC) count,

or a marked left shift in the WBC differential count were also excluded. Moreover, subjects with suspected or documented allergy or intolerance to implant materials were not included in the study. Surgeons were required to identify any allergic reactions to the material of the implant (information on the implant material is provided in the IMPLANT MATERIAL section) and exclude such subjects from the study.

Primary Objective

The primary objective of this study was to assess the rate of loosening of Pedicle Screw through postoperative radiological evaluation.

Secondary Objective

The secondary objective of this study was to evaluate functional Assessment of pedicle screw system by analyzing post-operative status of Oswestry Disability Index (ODI) and pain evaluation through Visual Analogue Scale (VAS). Safety of Device by record of any adverse event, serious adverse event and complication during follow up.

Primary Endpoints

The primary endpoints of this study include the use of X-ray radiographs to determine the rate of pedicle screw loosening.

Secondary Endpoints

The secondary endpoints focus on monitoring complications and adverse events, including fracture non-union, incision issues, infection, etc. These endpoints has been assessed at multiple time points, specifically at baseline, and at 1, 3, 6, and 12 months post operatively. Additionally, the Oswestry disability index (ODI) has been recorded to assess functional performance from baseline to the last follow-up. Pain levels has been measured using the Visual Analog Scale (VAS) with mean and standard deviation presented. The change in VAS score from baseline to each visit has been analyzed using paired t-tests at a significance level of 0.05.

Population Detail:

Summary of Demographics and Baseline Characteristics

Characteristics	Age (years)	Weight (kg)	Height(cm)	Body Mass Index (BMI)

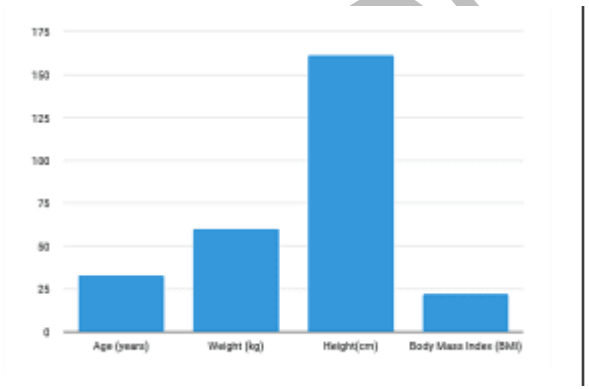
Mean	33.2	60.3	161.8	22.2
Range	18 - 58	43-82	154- 175	18.1-24.9

Gender distribution of study subjects

Male	7
Female	6

The study included a total of 13 subjects with a mean age of 33.2 years, ranging from 18 to 58 years. A significant proportion of the patients were above 30 years of age. Both males and females recruited in the study were almost equal, 7 males and 6 females. The mean weight of the subjects was 60.3 kg ranging from 43 to 82 kg. The mean BMI of the subjects was 22.2 kg/m^2. In terms of height, the subjects had an average of 161.8 cm ranging from 154 to 175 cm. These demographic and baseline characteristics are essential for understanding the composition of the study population and provide valuable insights for the interpretation of the study results.

The figures provides the information of demographic and baseline characteristics.



Study Method

The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the Pedicle Screw device. 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 159 subjects who met with Degenerative disc disease using Pedicle Screw device.

A Post-Market Clinical Follow-Up (PMCF) study was conducted to assess the safety and performance of the Pedicle screw device. This study was carried out after obtaining marketing (CE) approval, with the primary objective of evaluating the clinical performance, efficacy, and safety (including residual risks) of the device when used in accordance with its approved labeling. The study aimed to investigate various aspects, such as medium-term performance, the occurrence of clinical events, specific events related to defined patient populations, and the device's performance in a broader population of healthcare providers and patients needing spinal surgery.

The study consisted of up to seven study visits over a maximum period of 1 year. Subjects were expected to attend all study visits. All assessments were recorded and performed at Visit 1 to Visit 7 on all the study subjects. Subjects were screened for entry (Visit 1) and then were treated for the surgery (Visit 2). Subjects were assessed post-surgery for safety. Additional safety & effectiveness follow-up visits were occurred at 1, 3, 6 and 12 months. The final study visit was occured at Visit 7 i.e. at 12 months.

Study Result

As per interim data analysis, we have observed very significant positive results with respect to our device efficacy and safety. Overall, the study's findings suggest that the intervention led to significant pain reduction and enhanced functional performance in the patients. These improvements indicate the positive impact of the treatment on patients quality of life and recovery from their condition after intervention.

There are no any adverse event related to device in any medical device registry. The benefit-risk analysis has outweighed the benefit against the risk regarding the device.

6. Possible diagnostic or therapeutic alternatives.

The sensory function and movement can be tested by a few questions about the event that caused disability. But emergency diagnostic tests may be needed. They should be done if the injured person has neck pain, isn't fully awake, or has obvious weakness or neurological injury.

These tests can include:

- X-rays: X-rays can reveal damage to the bone surrounding the spinal cord, known as the vertebrae. They can also find tumors, fractures or changes in the

spine.

- CT scan: A CT scan can provide a clearer image compared with an X-ray. This scan uses computers to form a series of cross-sectional images that can define bone, disk and other changes.
- MRI: MRI uses a strong magnetic field and radio waves to produce computer-generated images. This test is helpful for looking at the spinal cord to find herniated disks, blood clots or other masses that might compress the spinal cord.

A few days after the injury, when some of the swelling might have gone down, a more comprehensive neurological exam may be done. The exam looks at the level and completeness of the injury. This involves testing muscle strength and ability to sense light touch and pinprick sensations.

Non-surgical Treatment

Most spinal injuries or disability require surgery to heal. But some injuries can be treated with physical therapy or medication.

Medication: A number of medications can be used to alleviate spinal pain, including non-steroidal anti-inflammatory drugs such as ibuprofen or Aleve, muscle relaxants, nerve medications, antidepressants and opioids.

Physical therapy: Working with a physical therapist can help you focus on core strengthening that can help relieve pain. They can also perform what is known as a range of motion assessment, which can help determine the severity of a patient's impairment.

Psychological treatment: There are different coping, relaxation, and distraction skills that can help patients better manage their chronic low back pain.

Surgical Treatment

Pedicle screw constructs have become one of the most commonly used procedures in spinal surgery. It has significantly improved the outcomes of spinal reconstructions that necessitate spinal fusion. Pedicle screws are placed above and below the vertebrae that were fused. The screw can be inserted either with the freehand technique or assisted with navigation technology. A rod is used to connect the screws, which prevents movement and allows the bone graft to heal. After the fusion is completely healed, the screws and rods can be removed. Removal isn't necessary unless they cause the patient discomfort. Short-segment surgical treatments based on pedicle screws have been shown to be practical, safe, and effective in the treatment of neoplastic, developmental, congenital, traumatic, and degenerative conditions. Pedicle-screw fixation can be effectively and safely used wherever a vertebral pedicle can accommodate a pedicle screw that is, in the cervical, thoracic, or lumbar spine. Complications such as screw loosening, screw pullout, and/or complete hardware failure may occur due to poor fixation strength of screw within the vertebrae. Previous studies reported that pedicle screw loosening rates after thoracolumbar stabilization

ranged from less than 1% to 15% in non-osteoporotic patients treated with rigid systems, and even higher in osteoporotic subjects or patients treated with dynamic systems. Radiological approaches, including X-ray and CT (computed tomography) scans, are used to assess pedicle screw loosening. Pedicle screw frameworks have been consistently altered in design and implantation strategies over a long period to reduce the incidence of screw breakage and improve the accessibility of connecting rod application.

Available treatments based on the severity and type of fracture diagnosed by the doctor:

Non-Surgical Treatment	Surgical Treatments
Medication, Physical Therapy, Psychological treatment	• Spinal Bone Plates, Screws and Rods • Spinal Cages • Any combination of these techniques.

7. Suggested profile and training for users.

The intended user (surgeon) should be well-qualified and must have gained sufficient training regarding the use of the device and should have experience in trauma surgery. The training materials i.e Surgical Technique, Instructions for Use, Catalog are already available on the manufacturer website (https://www.auxein.com/).

8. Reference to any harmonized standards and CS applied.

The following harmonized standards and guidance documents are applicable on Spinal Screw 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 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
7.	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.
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.

Non Harmonized Standards	
Standard	**Description**
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 17665-1:2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good Clinical Practice.
EN ISO 14602:2011	Non-active surgical implants - Implants for osteosynthesis - Particular Requirements.
EN ISO 14630:2012	Non-active surgical implants - General Requirements
EN ISO 11137-2:2015/A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.
EN ISO 11137-3:2017	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control (ISO 11137-3:2017)
EN ISO 11607-1:2020/A11:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
EN ISO 11607-2:2020/A11:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.

EN ISO 11737-1:2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
EN ISO 14644-1:2015	Clean-rooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.
EN 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.
EN ISO 14644-3:2019	Clean-rooms and associated controlled environments - Part 3: Test Methods.
EN ISO 14644-4:2022	Clean-rooms and associated controlled environments - Part 4: Design, construction and start-up.
EN ISO 14644-5:2004	Clean-rooms and associated controlled environments - Part 5: Operations
EN ISO 14644-7:2004	Clean-rooms and associated controlled environments - Part 7: Separative devices (clean air hoods, glove boxes, Isolators and mini).
EN ISO 14644-8 :2022	Clean-rooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration (ACC).
EN ISO 14644-9 :2022	Clean-rooms and associated controlled environments – Part 9: Classification of surface cleanliness by particle concentration.
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020).
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 5832-3:2021	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2021)
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-2: 2022	Biological evaluation of medical devices — Part 2: Animal welfare requirements
EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive

	toxicity
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2016	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 F1717-21	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
ASTM D4169-22	Standard Practice for Performance Testing of Shipping containers and System.
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 Guidelines	
Guidance Documents	Description
MDCG 2023-7	Practical Application of Article 61(4)
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 2023-7	Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR
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	01-03-2024	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)

A summary of the safety and clinical performance of the device, intended for patients, is given below:

Document revision: 00
Date issued: 01-03-2024

Device identification and general information

Device Trade Name: Auxein Spinal Screw 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: 08903993SS007N5

Year when the device was first CE-marked: 2014

Intended use of the device

Intended Purpose	The Spinal screw system is intended to maintain the anatomical integrity of the spine by adding extra support and strength to the fusion while it heals.
Indications of Use	VERTAUX 5.5mm Pedicle Screw System The VERTAUX 5.5mm Pedicle Screw System is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor and pseudarthrosis.

	VERTAUX Occipital System The VERTAUX Occipital System is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor and pseudarthrosis. VERTAUX Basico Polyaxial Screw The VERTAUX Basico Polyaxial Screw System is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor and pseudarthrosis. VERTAUX MIS Screw System The VERTAUX MIS Screw System is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor and pseudarthrosis. Osteobone Dual Threaded Screw The Osteobone Dual Threaded Screw is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor and pseudarthrosis.
Contraindications	Contraindications may be relative or absolute. The conditions listed below may preclude or reduce the chance of a successful outcome:

	○ Active infectious process or significant risk of infection (immunocompromise). ○ Signs of local inflammation. ○ Fever or leukocytosis. ○ Morbid obesity. ○ Pregnancy. ○ Mental illness. ○ Grossly distorted anatomy caused by congenital abnormalities. ○ Suspected or documented metal allergy or intolerance. ○ Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality. ○ Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance. ○ Any patient unwilling to follow postoperative instructions. ○ Any case not described in the indications.
Intended Patient Population	Skeletally mature Male and female patients aged 18 years to 60 Years.

Device description

The Spinal Bone Screws are used for treating the abnormality and disability of the spinal column. The Spinal screw system is intended to maintain the anatomical integrity of the spine by adding extra support and strength to the fusion while it heals. The spinal screws consist of various types of screws including VERTAUX 5.5mm Pedicle Screws System, VERTAUX Osteobone Dual Threaded Screws, VERTAUX Basico Polyaxial Screw, VERTAUX Occipital System, VERTAUX MIS Screw System. The details regarding Spinal Screw System can be found at www.auxein.com.

The more details are mentioned below:

Manufacturer's SRN	IN-MF-000018837		
Parameter	Details	Certified By	Certificate Number
Legacy Device	Yes, Spinal Screw System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	10000363901-PA-NA-IND Rev 2
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 EN ISO 5832-3:2021.
USFDA Approved	Yes (Spinal Screws are approved by USFDA whose details are as follow:) 510(k) Number: K201457
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-00000029
Notified Body Name and Single Identification Number	Name: DNV Product Assurance AS Single Identification Number: 2460

Principle of operation

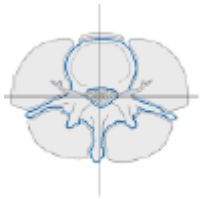
Spinal Screw System works on the AO Principle. The key concept involves:

1. Stability: Stabilization to achieve a specific therapeutic outcome
2. Alignment: Balancing the spine in three dimensions
3. Biology: Etiology, pathogenesis, neural protection, and tissue healing
4. Function: Preservation and restoration of function to prevent disability

The pedicle screw fixation devices allow the fusion of fewer motion segments in the treatment of spinal fractures compared to non-pedicular fixation system. Pedicle screw fixation system has been currently used in the surgical treatment of spinal deformities.

Step 1: Stability

Step 3: Biology



Step 2: Alignment

Step 4: Function

Description of Key functional elements:

Screw

The pedicle screw is a screw that is generally used treat the different types of spinal disorder like scoliosis, kyphosis. The screw is used around the pedicle region of vertebra. It has a unique shaped head called tulip and it is used to hold the rod. In some screw tulip is statically fixed and in some case is rotated in around 150 in all axis and called as polyaxial screw. Some of the screw are mono threaded while some are dual threaded.

Rod

The rod is used to provide the stabilization of the vertebra. It is fixed in the tulip of the screw with the help of the end cap.

Hook

The hook is one of the small components of the spinal screw system with significant importance. It is used to anchor the vertebra with the rod.

Cross link

Cross link is used to connect the both rod used for the stabilization with each other and provides the additional stability to the screw by increasing the rotational stiffness.

End Cap

End cap is used to the fix the rod in the tulip and prevent from the back out. Similarly, it also fixes the hook with the rod.

Risks and Warnings

A listing of Remaining Risk and undesirable effects includes, but is not limited to:

- Early or late loosening of any or all of the components.
- Disassembly, bending, or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, or general corrosion) including metallosis, staining, tumor formation, or autoimmune disease.
- Pressure on the skin from component in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, or pain.
- Bursitis.
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function (e.g. sensory or motor) including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, or visual deficits.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia paraparesis, reflex deficits, irritation, arachnoiditis, muscle loss.
- Urinary retention or loss of bladder control or other types of urological system compromise.

- Scar formation possibly causing neurological compromise or compression around nerves or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, or vertebral body) or bone graft or bone graft harvest site at, above, or below the level of surgery.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Non-union (or pseudarthrosis), delayed union, or mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Ileus, gastritis, bowel obstruction or loss of bowel control, or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Development of respiratory problems (e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.)
- Change in mental status.
- Death.

Warning & Precautions:

The safety and effectiveness of spinal Screw systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prostheses. In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend, or fracture as a result of exposure to every day mechanical stresses. A device that has been implanted should never be reprocessed or reused under any circumstances. Non-Sterile packaged devices should be sterilized before use. Reprocessing or reuse may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death.

The implantation of Spinal screw systems should be performed only by experienced spinal surgeons with specific training in the use of this screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient. 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. No spinal implant can 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 and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

Summary of any field safety corrective action, (FSCA including FSN) if applicable

Till now, regarding Auxein's Spinal Screw System there is no FSCA.

Summary of clinical evaluation and post-market clinical follow-up

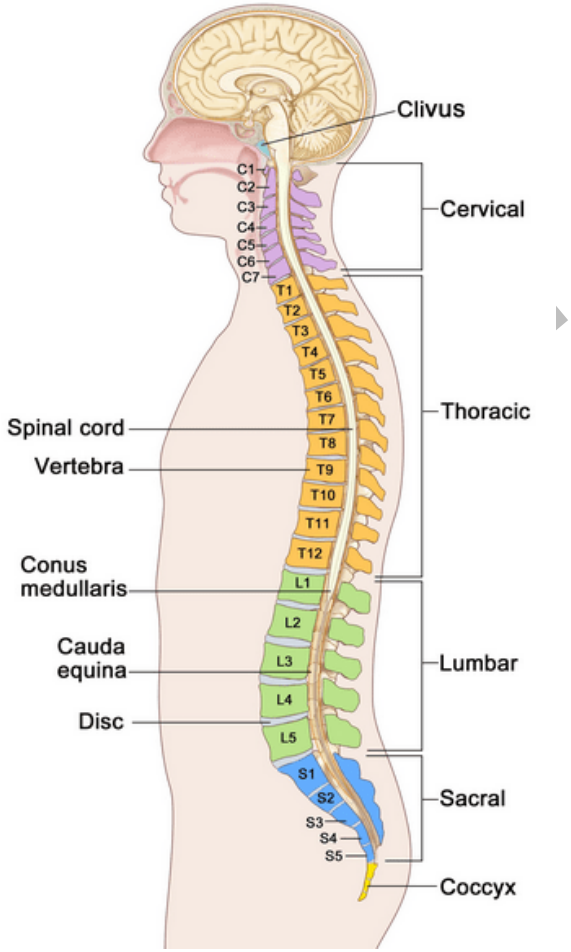
Clinical background of the device:

Description and consequences

The vertebral column, also known as the backbone or spine, is the core part of the axial skeleton in vertebrate animals.

Individual vertebrae are named according to their region and position. From top to bottom, the vertebrae are:

- Cervical spine: 7 vertebrae (C1–C7)
- Thoracic spine: 12 vertebrae (T1–T12)
- Lumbar spine: 5 vertebrae (L1–L5)
- Sacrum: 5 (fused) vertebrae (S1–S5)
- Coccyx: 4 (3–5) (fused) vertebrae (Tailbone)


Clivus
C1
C2
C3
C4
C5
C6
C7
Cervical
T1
T2
T3
T4
T5
T6
T7
T8
T9
T10
T11
T12
Thoracic
Spinal cord
Vertebra
Conus medullaris
L1
L2
L3
L4
L5
Lumbar
Cauda equina
Disc
S1
S2
S3
S4
S5
Sacral
Coccyx

Complications

- Early or late loosening of any or all of the components.
- Disassembly, bending, or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, or general corrosion) including metallosis, staining, tumor formation, or autoimmune disease.
- Pressure on the skin from component in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, or pain.
- Bursitis.
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function (e.g. sensory or motor) including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, or visual deficits.
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- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Development of respiratory problems (e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.)
- Change in mental status.
- Death.

Diagnosis and Treatment

The sensory function and movement can be tested by a few questions about the event that caused disability. But emergency diagnostic tests may be needed. They should be done if the injured person has neck pain, isn't fully awake, or has obvious weakness or neurological injury.

These tests can include:

- X-rays: X-rays can reveal damage to the bone surrounding the spinal cord, known as the vertebrae. They can also find tumors, fractures or changes in the
- CT scan: A CT scan can provide a clearer image compared with an X-ray. This scan uses computers to form a series of cross-sectional images that can define bone, disk and other changes.
- MRI: MRI uses a strong magnetic field and radio waves to produce computer-generated images. This test is helpful for looking at the spinal cord to find herniated disks, blood clots or other masses that might compress the spinal cord.

A few days after the injury, when some of the swelling might have gone down, a more comprehensive neurological exam may be done. The exam looks at the level and completeness of the injury. This involves testing muscle strength and ability to sense light touch and pinprick sensations.

Pain Management

Surgeon will give a prescription for pain medicines. Get it filled when you go home so you have it available. Take the medicine before the pain becomes very bad. If you will be doing an activity, take the medicine about half an hour before you start.

Rehabilitation and Return to Activity

You will need to change how you do some things. Try not to sit for longer than 20 or 30 minutes at one time. Sleep in any position that does not cause back pain. Your surgeon will tell you when you can resume sexual activity.

You may be fitted for a back brace or corset to help support your back:

- Wear the brace when you are sitting or walking and as instructed by your surgeon.
- You do not need to wear the brace when you are sitting on the side of the bed for a short time or using the bathroom at night.

Do not bend at the waist. Instead, bend your knees and squat down to pick up something. Do not lift or carry anything heavier than around 10 pounds or 4.5 kilograms (about 1 gallon or 4 liters of milk). This means you should not lift a laundry basket, grocery bags, or small children. You should also avoid lifting something above your head until your fusion heals.

Other activity:

- Take only short walks for the first 2 weeks after surgery. After that, you may slowly increase how far you walk.
- You may go up or down stairs once a day for the first 1 or 2 weeks, if it does not cause much pain or discomfort.
- Do not start swimming, golfing, running, or other more strenuous activities until you see your health care provider. You should also avoid vacuuming and more strenuous household cleaning.

Your surgeon may prescribe physical therapy so that you learn how to move and do activities in a way that prevents pain and keeps your back in a safe position. These may include how to:

- Get out of bed or up from a chair safely
- Get dressed and undressed
- Keep your back safe during other activities, including lifting and carrying items
- Do exercises that strengthen your back and abdominal muscles to keep your back stable and safe

Your surgeon and physical therapist can help you decide whether or when you can return to your previous job.

Riding or driving in a car:

- Do not drive for the first 2 weeks after surgery. After 2 weeks, you may take short trips only if your surgeon says it's OK.
- Travel only for short distances as a passenger in a car. If you have a long ride home from the hospital, stop every 30 to 45 minutes to stretch a bit.

Clinical Evidence/Safety of the device

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, multi-centric, post marketing clinical follow-up study to evaluate the safety and performance of pedicle screws in patient with spinal disorders.

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
CR_PMCF/P_01	Ongoing	INDIA	13/159	0	0	0
Study Title	A prospective single arm, multi-centric, post marketing clinical follow-up study to evaluate the safety and performance of pedicle screws in patient with spinal disorders.					
CTRI Number	CTRI/2023/03/051092					
CTRI Registration Date	27/03/2022					
Number of study sites	Two					
Name of Study Sites	a. Lok Nayak Hospital, New-Delhi, India and b. Stavya Spine Hospital & Research Institute Ellis Bridge, Gujarat, India					
No. of Patients enrolled	13					

Study design: The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the Pedicle Screw device. 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 159 subjects who met with Degenerative disc disease using Pedicle Screw device.

Inclusion criteria

Male and female subjects aged 18 years to 60 Years, who had pedicle placement surgery and were willing to attend all study visits, were recruited for this study. Prior to enrollment, written informed consent for participation was obtained from all the study subjects.

Exclusion criteria

Subjects with pedicle deformity were not eligible for participation in the study. Additionally, subjects with the history Neurofibromatosis type 2 were excluded. Those with metabolic disorder that could pose a high risk of fixation failure or complications in postoperative care, any other condition that could hinder the potential benefits of implant insertion surgery and disrupt the normal process of bone remodeling (e.g., the presence of tumors or congenital abnormalities, fractures local to the operating site), elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell (WBC) count, or a marked left shift in the WBC differential count were also excluded. Moreover, subjects with suspected or documented allergy or intolerance to implant materials were not included in the study. Surgeons were required to identify any allergic reactions to the material of the implant (information on the implant material is provided in the IMPLANT MATERIAL section) and exclude such subjects from the study.

Primary Objective

The primary objective of this study was to assess the rate of loosening of Pedicle Screw through postoperative radiological evaluation.

Secondary Objective

The secondary objective of this study was to evaluate functional Assessment of pedicle screw system by analyzing post-operative status of Oswestry Disability Index (ODI) and pain evaluation through Visual Analogue Scale (VAS). Safety of Device by record of any adverse event, serious adverse event and complication during follow up.

Primary Endpoints

The primary endpoints of this study include the use of X-ray radiographs to determine the rate of pedicle screw loosening.

Secondary Endpoints

The secondary endpoints focus on monitoring complications and adverse events, including fracture non-union, incision issues, infection, etc. These endpoints

has been assessed at multiple time points, specifically at baseline, and at 1, 3, 6, and 12 months post operatively. Additionally, the Oswestry disability index (ODI) has been recorded to assess functional performance from baseline to the last follow-up. Pain levels has been measured using the Visual Analog Scale (VAS) with mean and standard deviation presented. The change in VAS score from baseline to each visit has been analyzed using paired t-tests at a significance level of 0.05.

Population Detail:
Summary of Demographics and Baseline Characteristics

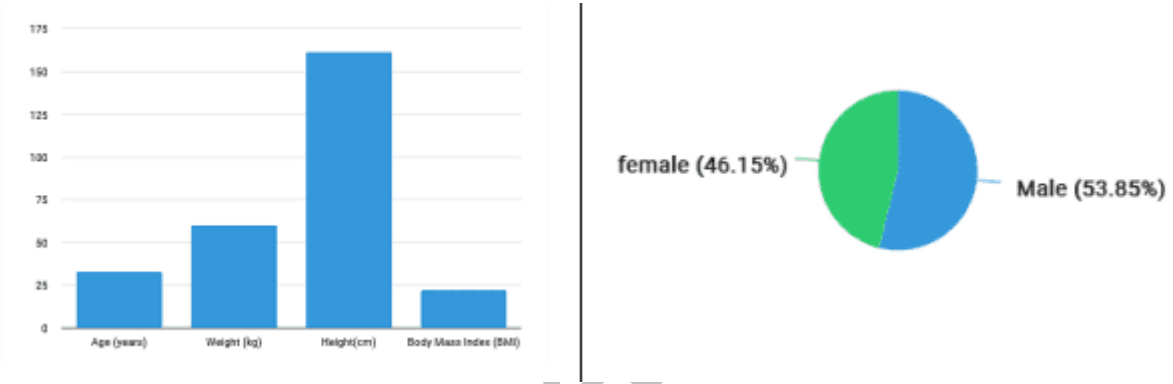
Characteristics	Age (years)	Weight (kg)	Height(cm)	Body Mass Index (BMI)
Mean	33.2	60.3	161.8	22.2
Range	18 - 58	43-82	154- 175	18.1-24.9

Gender distribution of study subjects

Male	7
Female	6

The study included a total of 13 subjects with a mean age of 33.2 years, ranging from 18 to 58 years. A significant proportion of the patients were above 30 years of age. Both males and females recruited in the study were almost equal, 7 males and 6 females. The mean weight of the subjects was 60.3 kg ranging from 43 to 82 kg. The mean BMI of the subjects was 22.2 kg/m^2. In terms of height, the subjects had an average of 161.8 cm ranging from 154 to 175 cm. These demographic and baseline characteristics are essential for understanding the composition of the study population and provide valuable insights for the interpretation of the study results.

The figures provides the information of demographic and baseline characteristics.



Study Method

The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the Pedicle Screw device. 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 159 subjects who met with Degenerative disc disease using Pedicle Screw device.

A Post-Market Clinical Follow-Up (PMCF) study was conducted to assess the safety and performance of the Pedicle screw device. This study was carried out after obtaining marketing (CE) approval, with the primary objective of evaluating the clinical performance, efficacy, and safety (including residual risks) of the device when used in accordance with its approved labeling. The study aimed to investigate various aspects, such as medium-term performance, the occurrence of clinical events, specific events related to defined patient populations, and the device's performance in a broader population of healthcare providers and patients needing spinal surgery.

The study consisted of up to seven study visits over a maximum period of 1 year. Subjects were expected to attend all study visits. All assessments were recorded and performed at Visit 1 to Visit 7 on all the study subjects. Subjects were screened for entry (Visit 1) and then were treated for the surgery (Visit 2). Subjects were assessed post-surgery for safety. Additional safety & effectiveness follow-up visits were occurred at 1, 3, 6 and 12 months. The final study visit

was occured at Visit 7 i.e. at 12 months.

Study Result

As per interim data analysis, we have observed very significant positive results with respect to our device efficacy and safety. Overall, the study's findings suggest that the intervention led to significant pain reduction and enhanced functional performance in the patients. These improvements indicate the positive impact of the treatment on patients quality of life and recovery from their condition after intervention.

There are no any adverse event related to device in any medical device registry. The benefit-risk analysis has outweighed the benefit against the risk regarding the device.

6. **Possible diagnostic or therapeutic alternatives**

The sensory function and movement can be tested by a few questions about the event that caused disability. But emergency diagnostic tests may be needed. They should be done if the injured person has neck pain, isn't fully awake, or has obvious weakness or neurological injury.

These tests can include:

- X-rays: X-rays can reveal damage to the bone surrounding the spinal cord, known as the vertebrae. They can also find tumors, fractures or changes in the spine.
- CT scan: A CT scan can provide a clearer image compared with an X-ray. This scan uses computers to form a series of cross-sectional images that can define bone, disk and other changes.
- MRI: MRI uses a strong magnetic field and radio waves to produce computer-generated images. This test is helpful for looking at the spinal cord to find herniated disks, blood clots or other masses that might compress the spinal cord.

A few days after the injury, when some of the swelling might have gone down, a more comprehensive neurological exam may be done. The exam looks at the level and completeness of the injury. This involves testing muscle strength and ability to sense light touch and pinprick sensations.

Non-surgical Treatment

Most spinal injuries or disability require surgery to heal. But some injuries can be treated with physical therapy or medication.

Medication: A number of medications can be used to alleviate spinal pain, including non-steroidal anti-inflammatory drugs such as ibuprofen or Aleve,

muscle relaxants, nerve medications, antidepressants and opioids.

Physical therapy: Working with a physical therapist can help you focus on core strengthening that can help relieve pain. They can also perform what is known as a range of motion assessment, which can help determine the severity of a patient's impairment.

Psychological treatment: There are different coping, relaxation, and distraction skills that can help patients better manage their chronic low back pain.

Surgical Treatment

Pedicle screw constructs have become one of the most commonly used procedures in spinal surgery. It has significantly improved the outcomes of spinal reconstructions that necessitate spinal fusion. Pedicle screws are placed above and below the vertebrae that were fused. The screw can be inserted either with the freehand technique or assisted with navigation technology. A rod is used to connect the screws, which prevents movement and allows the bone graft to heal. After the fusion is completely healed, the screws and rods can be removed. Removal isn't necessary unless they cause the patient discomfort. Short-segment surgical treatments based on pedicle screws have been shown to be practical, safe, and effective in the treatment of neoplastic, developmental, congenital, traumatic, and degenerative conditions. Pedicle-screw fixation can be effectively and safely used wherever a vertebral pedicle can accommodate a pedicle screw that is, in the cervical, thoracic, or lumbar spine. Complications such as screw loosening, screw pullout, and/or complete hardware failure may occur due to poor fixation strength of screw within the vertebrae. Previous studies reported that pedicle screw loosening rates after thoracolumbar stabilization ranged from less than 1% to 15% in non-osteoporotic patients treated with rigid systems, and even higher in osteoporotic subjects or patients treated with dynamic systems. Radiological approaches, including X-ray and CT (computed tomography) scans, are used to assess pedicle screw loosening. Pedicle screw frameworks have been consistently altered in design and implantation strategies over a long period to reduce the incidence of screw breakage and improve the accessibility of connecting rod application.

Available treatments based on the severity and type of fracture diagnosed by the doctor:

Non-Surgical Treatment	Surgical Treatments
Medication, Physical Therapy, Psychological treatment	• Spinal Bone Plates, Screws and Rods • Spinal Cages • Any combination of these techniques.

7. **Suggested profile and training for users**

The intended user (surgeon) should be well-qualified and must have gained sufficient training regarding the use of the device and should have experience in trauma surgery. The training materials i.e Surgical Technique, Instructions for Use, Catalog are already available on the manufacturer website (https://www.auxein.com/).