DEVICE SYSTEM NAME

Spinal Screw System

DEVICE DESCRIPTION

Auxein's spinal screw system is a group of specifically designed metallic bone screw used for the stabilization of the spinal column. Spinal 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. 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. These screws consist of a wide range of sizes for patients. It is also available in Titanium material (EN ISO 5832-3:2021). All the components are passed through the rigorous quality checks and stringent tests to verify their quality, safety and effectiveness like mechanical test, biocompatibility test, chemical test and post market use.

The following are the categories of the spinal screw system:

1. **VERTAUX 5.5mm Pedicle Screw System**

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

2. **VERTAUX Osteobone Dual Thread Screw**

a. OSTEOBONE Multiaxial Pedicle Fenestrated Dual Thread Screw, Titanium
b. OSTEOBONE - Pedicle Screw Cap M9, Titanium

3. **VERTAUX Occipital System**

a. VERTAUX - Occipital Polyaxial Pedicle Screw, Titanium
b. VERTAUX - Occipital Polyaxial Pedicle Screw, Partial Thread, Titanium
c. VERTAUX - Occipital Inner Screw Cap(M6), Titanium
d. VERTAUX - Occipital Pre Bent Rod, Ø3.2mm, Titanium
e. VERTAUX - Occipital Laminar Hook, Titanium
f. VERTAUX - Occipital Straight Rod, Titanium

g. VERTAUX - Occipital Crosslink, Titanium
h. VERTAUX - Occipital Lateral Offset Connector, Titanium
i. VERTAUX - Occipital Plate, Titanium
j. VERTAUX - Occipital Pre Bent Rod for Plate, Titanium
k. VERTAUX - Occipital Screw, Titanium
l. Universal Connector

4. **VERTAUX Basico Polyaxial Screw**

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

5. **VERTAUX MIS Screw System**

a. Vertaux MIS Polyaxial Screw with Cap, Titanium
b. Vertaux MIS Inner Screw Cap
c. Vertaux MIS Monoaxial Screw with Cap, Titanium
d. Vertaux MIS Pre Bend Rod, Titanium
e. Vertaux MIS Straight, Titanium

MATERIALS

The Spinal Screw System are made from Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021. This material is not compatible with other metal alloys.

INTENDED USE/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

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 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.

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.

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.

The above-mentioned list does not exhaust the topic of contraindications..

WARNINGS & 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. Sterile packaged devices should also never be re sterilized. 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.

TARGET PATIENT GROUP

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. Before enrollment, written informed consent for participation was obtained from all the study subjects.

INTENDED USER GROUP

The Spinal screw system is recommended to be used by only well-trained, certified and experienced surgeons.

SURGEON NOTE

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

CAUTION

- For use on or by the order of a surgeon only.
- Federal law (USA) restricts these devices to sale by or on the order of a physician.

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.

All Auxein's spinal screw is manufactured in metallic material and does not emit any ionizing radio-active radiation.

CLINICAL BENEFITS

If the device is implanted as per the labeling and recommended technique, then it helps to achieve anatomical stabilization, fracture fusion by radiological evaluation of the spinal column by reducing pain (VAS Score), and minimizing Oswestry Disability Index (ODI).

PERFORMANCE CHARACTERSTICS

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

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The link to Summary of Safety and Clinical Performance (SSCP) will be updated in this Instructions for Use when the SSCP will be made available to the EUDAMED Database.

POTENTIAL ADVERSE EVENTS

A listing of possible 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.

NOTE: Additional surgery may be necessary to correct some of these potential adverse events.

OTHER PREOPERATIVE, INTRAOPERATIVE, AND POSTOPERATIVE WARNINGS ARE AS FOLLOWS

PREOPERATIVE:

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and pre dispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
- An adequate inventory of implants should be available at the time of surgery; normally a quantity in excess of what is expected to be used.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify all parts and necessary instruments are present before surgery. The Spinal Screw System components are not to be combined with the components from another manufacturer.

INTRA-OPERATIVE:

- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- The rods should not repeatedly be or excessively bent. The rods should not be reverse-bent in the same location. Use great care to ensure the implant surfaces are not scratched or notched since

such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.

- Utilize an imaging system to facilitate surgery.
- Caution: do not overtap or use a screw that is either too long or too large. Overtapping, using an incorrectly sized screw, or accidentally advancing the guidewire during tap or screw insertion may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screws are being inserted into spinal pedicles, use as large a screw diameter as will fit into each pedicle.
- Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws, especially screws or nuts that have a break-off feature. Once this is completed, go back and firmly tighten all of the screws and nuts. Recheck the tightness of all nuts or screws after finishing to make sure none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

POST-OPERATIVE

The Surgeon's postoperative directions and warnings to the patient and the corresponding patient compliance are crucial.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening, and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco, utilize nicotine products, or consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone healing process.
- The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, or break, the device(s) should be revised or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- The Spinal Screw System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the

spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) migration of implant position possibly resulting in injury; (2) risk of additional injury from post operative trauma; (3) bending, loosening, and breakage which could make removal impractical or difficult; (4) pain, discomfort, or abnormal sensations due to the presence of the device; (5) possible increased risk of infection; (6) bone loss due to stress shielding; Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.

- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the Spinal Screw System components should never be reused under any circumstances.

PACKAGING

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

STERILIZATION

AUXEIN MEDICAL'S Spinal Screw System is supplied Sterile. A sterility assurance level SAL 10^{-6} was achieved using Gamma irradiation sterilization with minimum dose of 25kGy. Check the integrity of the packaging and labeling before opening the pack.

STORAGE

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

DISPOSAL

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

PRODUCT COMPLAINTS

Customers or users of products, who have any complaints or who have experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the Manufacturer, AUXEIN MEDICAL or EU Representative. Further, if any of the implanted Spinal Screw System ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the Manufacturer or EU Representative should be notified immediately.

If any AUXEIN MEDICAL's product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and

number, lot number(s), your name and address, the nature of the complaint and notification of whether a written reportfrom the distributor is requested.

FURTHER INFORMATION

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

DETAILS OF VARIOUS SYMBOLS USED IN LABELING

Symbol	Symbol Title	Description	Standard Title	Reference Number
	Date of Manufacture	Indicates the date when the medical device was manufactured.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.3
	Manufacturer	Indicates the medical device manufacturer	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.1
	Authorized representative in the European community	Indicates the authorized representative in the European Community/European Union	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.2
	Reorder Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.6
	Conformité Européene (European Conformity)	Signifies European technical conformity.	EU MDR 2017/745.	MDD 93/42/EEC, MDR 2017/745 (Annex XII, Article 20)

	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.5
	Do Not Reuse	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.4.2
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.4
	Keep away from the sunlight	Indicates a medical device that needs protection from light sources	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.3
	Do not use if package is damaged.	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.8
	Do not re-sterilize	Indicates a medical device that has already subjected to a sterilization process, so do not re-sterilize.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.6

	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.4
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.7
	Quantity	Indicates quantity of medical devices contained within the packaging.	N/A	N/A
	Use by date	Indicates the date after which the medical device is not to be used.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.4
	Prescription only	The symbol for Prescription Device Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	N/A	21 CFR 801.15 ad 21 CFR 801.109 ((c) (1) (i) (F) (b) (1)).
	Medical device	Indicates the item is a medical device	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.7.7
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.7.10

CE

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

Manufactured By:

AUXEIN MEDICAL PVT. LTD.

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Revision History Table:

S. No.	Document No	Rev. No.	Description of Revision	Effective date	Prepared by	Approved by
1.	AMPL-IFU-SSS/S-007	00	Initially released	01-03-2024		