Instructions for Use
STERILE SPINE™ ACP
Anterior Cervical Plate System

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Anterior Cervical Plate System

Manufacturer:
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CAUTION: Federal law restricts this device to sale by or on the order of a physician.

	5.1.1	Manufacturer
	5.1.3	Date of Manufacture
	5.1.4	Use-by-date
LOT	5.1.5	Batch code
REF	5.1.6	Catalogue number
STERILE R	5.2.4	Sterilized using Irradiation
	5.2.6	Do not resterilize
	5.2.8	Do not use if package is damaged
	5.4.2	Do not re-use
	5.4.3	Consult instructions for use
	5.4.4	Caution
	5.2.12	Double Sterile Barrier System
LATEX		Not made with latex
Rx only		Prescription Use Only

Symbols: ISO-15223-1:2021

DESCRIPTION
The STERILE SPINE™ ACP Anterior Cervical Plate System consists of a variety of bone plates and self-tapping bone screws (available in several diameters) composed of titanium alloy (Ti6Al-4V ELI). A bone screw locking mechanism assembled to the plate eliminates the need to assemble loose locking components during surgery. The bone screws are used to form a tightly locked construct on vertebral bodies of the cervical spine during the development of a cervical spinal fusion. The implants can be installed with any suitable instruments. A sterile procedural package is available for use. Certain products are available separately as sterile packed ancillary devices, please contact your sales representative to determine what is available in your region.

INDICATIONS FOR USE
The STERILE SPINE™ ACP Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine (C2-C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neckpain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (including fractures), spinal stenosis, tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthroses, and/or failed previous fusions.

WARNING: This device system is intended for anterior cervical interbody fusions only. This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

CONTRAINDICATIONS
1. Infection local to the operative site.
2. Signs of local inflammation or open wounds adjacent to the operative site.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Mental illness, alcoholism or drug abuse.
6. Pregnancy.
7. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
9. Suspected or documented metal sensitivity, allergy, intolerance, or foreign body sensitivity.
10. Patients with inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
11. Any case not described in the Indications for Use.
12. Any patient unwilling to cooperate with the post-operative instructions.

IMPORTANT NOTE
These implants are intended only to assist healing and are not intended to replace normal body structures. Delayed union or nonunion of bone in the presence of weight bearing or load bearing, could eventually break the implant due to metal fatigue. Therefore, it is important that immobilization of the operative site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. The surgeon must be thoroughly knowledgeable in the medical, surgical, mechanical, and metallurgical aspects of the implants. Postoperative care is extremely important. The patient should be warned that non-compliance with postoperative instructions could lead to breakage of the implant and/or possible migration requiring revision surgery to remove the device. Implants are provided sterile and instruments are provided in sterile procedural kit.

WARNINGS
1. This device system is intended for anterior cervical interbody fusions only.
2. This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
3. Selection of the proper size, shape and design of the implant increases the potential for success. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants.
4. Laboratory fatigue testing has shown a relationship between device loading and device performance which makes patient selection factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions and their effect on the load and number of cycles to which the implant is subjected crucial to surgical success.
5. These devices are not designed to withstand the unsupported stress of full weight bearing or load bearing and cannot withstand activity levels and/or loads equal to those placed on normal healthy bone. If healing is delayed or does not occur, the implant could eventually break due to metal fatigue. Loads produced by weight bearing and activity levels will dictate the longevity of the implant.
6. Contact of dissimilar metals accelerates the corrosion process, which could enhance fatigue fracture of the implants. Therefore, only use like or compatible metals with implants that are in contact with each other. Stainless steel and titanium implant components must not be used together in a construct. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the STERILE SPINE™ ACP Anterior Cervical Plate by the surgeon. A successful surgical result is not always achieved. This is especially true in spinal surgery where many extenuating circumstances may compromise the results. The STERILE SPINE™ ACP Anterior Cervical Plate System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the STERILE SPINE™ ACP Anterior Cervical Plate System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. 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, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion. Postoperative care is extremely important. The patient should be warned that non-compliance with postoperative instructions could lead to breakage of the implant and/or possible migration requiring revision surgery to remove the device.

IMPLANT SELECTION
The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to dynamic stresses in use, and their design strength is limited by anatomical constraints. Unless great care is taken in patient selection, proper implant placement, and postoperative management to minimize stresses on the implant, the dynamic stresses may cause metal fatigue and consequent breakage, bending or loosening of the implant before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PRECAUTIONS
1. This implant system is intended for single-use only. Never re-implant an explanted metal device, under any circumstances. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
2. Titanium implants are to be handled with care. If contouring of the plate is required, avoid sharp

bends and reverse bends. Avoid notching or scratching of the device, which could produce internal stresses and lead to early breakage.

3. After healing is complete, the implant may be removed since it is no longer necessary. Implants which are not removed may result in complications such as implant loosening, fracture, corrosion, migration, pain or stress shielding of bone; particularly in young, active patients. Implant removal should be followed by adequate postoperative management.
4. Adequate patient instruction must include instructing the patient on the limitations of the metallic implant. The patient should be cautioned regarding physical activity and weight bearing or load bearing prior to complete healing.
5. This device is recommended for use by surgeons thoroughly familiar with the relative current literature, surgical techniques, implantation technique for this device, and postoperative care of the patient.
6. This is a single-use device. Never reuse an implant or instrument. Reuse can result in the transfer of materials not limited to bone, tissue, blood or infectious disease. Although the device may appear undamaged, previous stresses may have created non-visible damage that could result in device failure. The manufacturer accepts no responsibility for a reused implant or instrument.
7. Devices are provided sterile; resterilization of the device has not been validated by WishBone Medical.

POTENTIAL ADVERSE EFFECTS

1. Nonunion (pseudarthroses), delayed union, or malunion.
2. Early or late loosening of any or all of the components.
3. Bending, fracture, disassembly, breakage, or migration of any or all of the components of the implant.
4. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
5. Decrease in bone density due to stress shielding, bone loss or decrease in bone density, possibly caused by stress shielding.
6. Graft donor site complications including pain, fracture, or wound healing problems. Resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
7. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
8. Pain, discomfort, or abnormal sensations due to presence of the implant.
9. Nerve, soft tissue, bursitis, or blood vessel damage due to surgical trauma and/or improper positioning and placement of implants or instruments.
10. Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation. Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
11. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
12. Fracture of bony structures.
13. Spinal cord impingement.
14. Dural leak.
15. Necrosis of bone.
16. Hemorrhage.
17. Infection.
18. Loss of bowel and/or bladder control or other types of urological system compromise.
19. Scar formation possibly causing neurological compromise around nerves and/or pain.
20. Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
21. Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
22. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
23. Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
24. Change in mental status.
25. Death.

Note: Additional surgery may be necessary to correct some of these anticipated adverse events. Other preoperative, intraoperative, and postoperative warnings are as follows:

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. See “How Supplied/Storage” and “Inspection” sections.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
5. The STERILE SPINE™ ACP Anterior Cervical Plate System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.

INTRAOPERATIVE

1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
3. When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at the same location.
4. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
5. Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
7. Before closing the soft tissues, all of the screws should be seated onto the plate. Recheck the tightness of all screws after finishing to make sure that none have loosened during the tightening of the other screws. Also secure the locking screw into place to secure the portion of the screw heads which are located at the ends of the plate. Failure to do so may result in screw loosening. Caution: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. 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 or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive 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, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
3. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. 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 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. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
5. The STERILE SPINE™ ACP Anterior Cervical Plate System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and should be removed. 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:
   a. Corrosion, with localized tissue reaction or pain,
   b. Migration of implant position possibly resulting in injury,
   c. Risk of additional injury from post-operative trauma,
   d. Bending, loosening and/or breakage, which could make removal impractical or difficult,
   e. Pain, discomfort, or abnormal sensations due to the presence of the device,
   f. Possible increased risk of infection, and
   g. Bone loss due to stress shielding.

   While the surgeon must make the final decision on implant removal, whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal should be followed by adequate postoperative management to avoid fracture.
6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none

of the STERILE SPINE™ ACP Anterior Cervical Plate System components should ever be reused under any circumstances.

STERILIZATION

Implants and instruments are sterilized by gamma irradiation or ethylene oxide, as indicated on their package label. Do not resterilize. This is a single-use device. Reuse or reprocessing (e.g., cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death. Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user. This device is provided sterile, and resterilization of the device has not been validated.

HOW SUPPLIED/STORAGE

The implant and instrument devices are packed in protective packaging that is labeled to its contents. All implants and instruments are supplied sterile:

- Always store the devices in the original protective packaging.
- Store the devices in a dry and dust-free place (standard hospital environment).

INSPECTION

Before use, inspect the implant or instrument packaging carefully. Do not use when sterile barrier is visibly open or damaged.

MRI SAFETY INFORMATION

These devices have not been evaluated for safety in the MR environment. The system has not been tested for heating or unwanted movement in the MR environment. The safety of these devices 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.

FOR USE BY A TRAINED PHYSICIAN

This description alone does not provide sufficient background for direct use of WishBone Medical products. Instruction by a surgeon experienced in handling these products is highly recommended. It is the responsibility of the surgeon to be familiar with the instrumentation, method of application, and recommended surgical techniques before use of these products by reviewing relevant publications and surgical techniques.

The STERILE SPINE ACP Anterior Cervical Plate System Surgical Technique describing the uses of the system can be found at www.unifiedspine.com

PRODUCT COMPLAINTS

Any Health Care Professional (e.g. customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify their sales representative or distributor. When filing a complaint, please provide the following information:

- Nature of the complaint
- Location of the incident
- Name and address of complainant
- Device name(s) and part number(s)
- Device lot number(s)
- Device UDI (if available)
- Patient name or patient identifier
- Patient age & gender

FOR FURTHER INFORMATION

Please contact Unified Spine, Inc. for further information about this product.

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