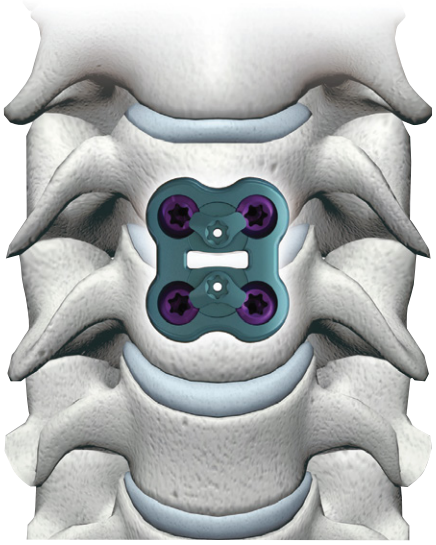
SURGICAL TECHNIQUE GUIDE

ONE SURGICAL®
Foundation to Innovation



AVEM

Cervical Plate System

System Overview

INTRODUCTION

The One Surgical Avem Anterior Cervical Plate system is intended for anterior cervical intervertebral body screw fixation from C2 to T1. Rigid fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.

Implant components consist of a variety of shapes and sizes of plates, bone screws and associated instruments. Locking caps are pre-assembled to the plates. They cover the heads of the bone screws to reduce the potential for screw back-out.

With this locking mechanism, implant components can be rigidly locked into many different configurations to suit the individual pathology and anatomical conditions of the mature patient.

They are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

Implants must not be used with the components from any other system or manufacturer in a construct.

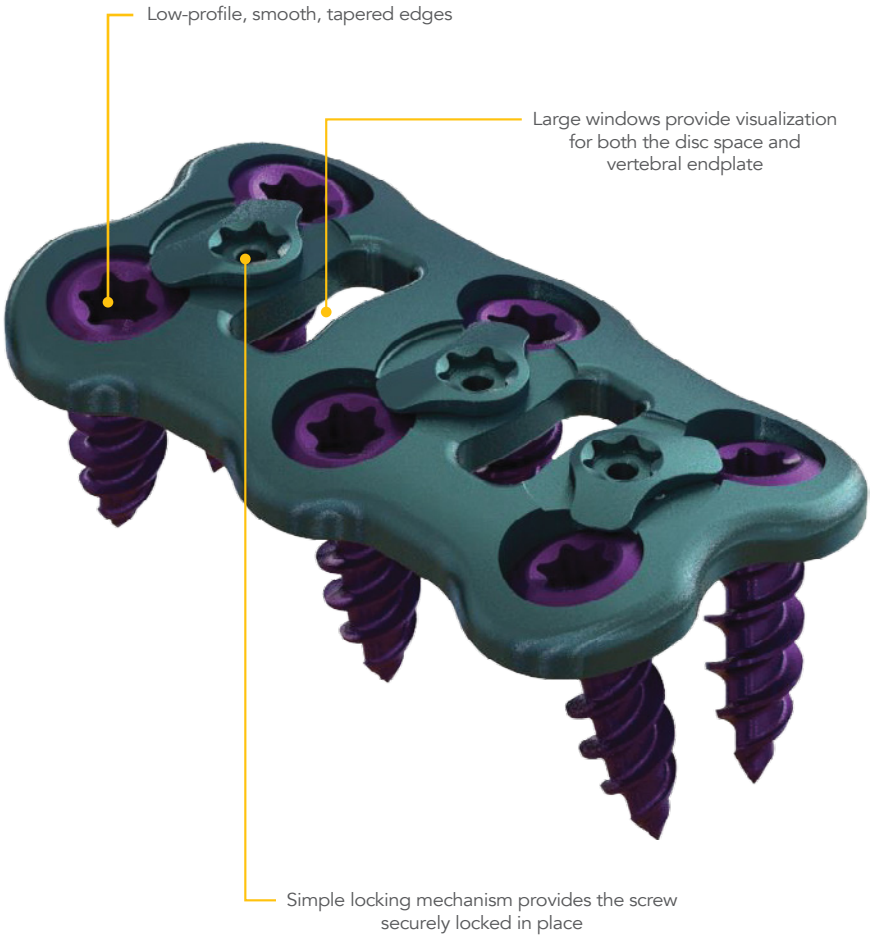
INDICATION

The One Surgical Avem Anterior Cervical Plate system is intended for anterior interbody screw fixation from C2 to T1.

The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with:

1. Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Spondylolisthesis
3. Trauma (including fractures)
4. Spinal Stenosis
5. Tumors
6. Deformity (defined as kyphosis, lordosis, or scoliosis)
7. Pseudarthrosis, and/or 8) failed previous fusions

System Overview



The One Surgical Avem Anterior Cervical Plate system is an innovative cervical plate solution. It offers direct visualization of implant placement and screw locking.

With its generous graft window, low profile, simple locking mechanism, narrow waist and aggressive self-drilling screws.

This system provides a complete solution in one user-friendly implant.

Operative Technique

STEP 1: SITE PREPARATION

The patient is placed in the supine position with the neck supported posteriorly to achieve normal segmental lordosis.

A standard incision is used to access the cervical spine, and the longis colli muscles are elevated with medial/lateral retractor blades.

Cranial/caudal retractor blades may also be used.

STEP 2: PLATE SIZE SELECTION

The Avem Anterior Cervical Plates from 1 to 5 levels ranging from 8 to 91mm (Hole-to-Hole).

Measurements are taken from the center hole of the cephalad level to the center hole of the caudad level.

- Using the plate holder, position the appropriate plate on the vertebral column to confirm its suitability (Figure 3). When the plate is properly sized and positioned, the superior screw holes should align with the inferior of the superior vertebral body.

  The inferior screw holes should align with the superior of the inferior vertebral body.

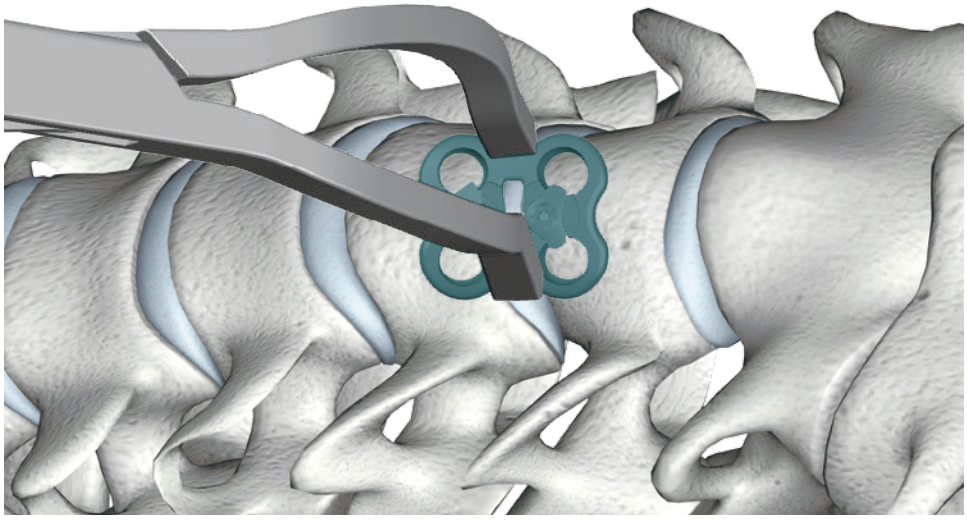
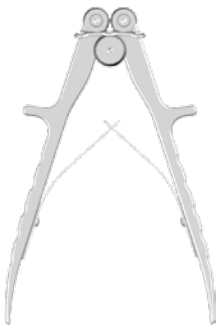


Figure 1

STEP 3: PLATE CONTOURING

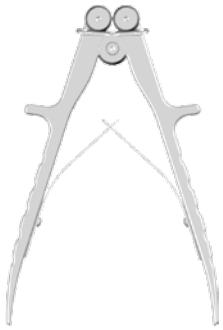
The Avem Anterior Cervical Plates are pre-bent When additional contouring is reguired, insert the plate into the plate bender (Figure 2, 3) and squeeze the handles.

- The Avem Anterior Cervical Plate is provided with CAP LOC mechanism should be bent across the bend zones (Figure 4).
- Plates should be bent in one direction, kyphosis or lordosis only.
  Never reverse the bend as this may create micro fractures that will weaken the plate.
- Short plates of each level do not have bend zones and therefore cannot be bent.



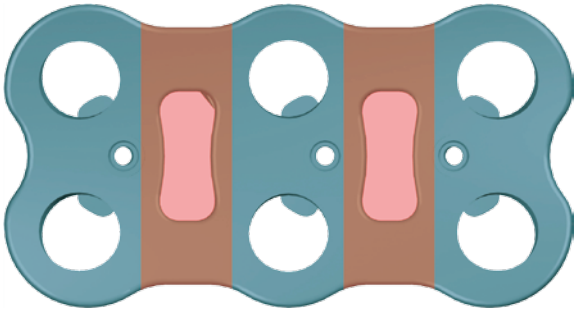
Increase lordotic curvature

Figure 2



Decrease lordotic curvature

Figure 3



Bend zone **Bend zone**

Figure 4

STEP 4: POSITION PLATE AND INSERT TEMPORARY FIXATION PINS

Using the Temporary Fixation Pin inserter, re-position the plate on the vertebral bodies. Insert a temporary fixation pin, available in threaded shaft options, into one of the cephalad and one of the caudad screw bores of the plate (Figure 5).

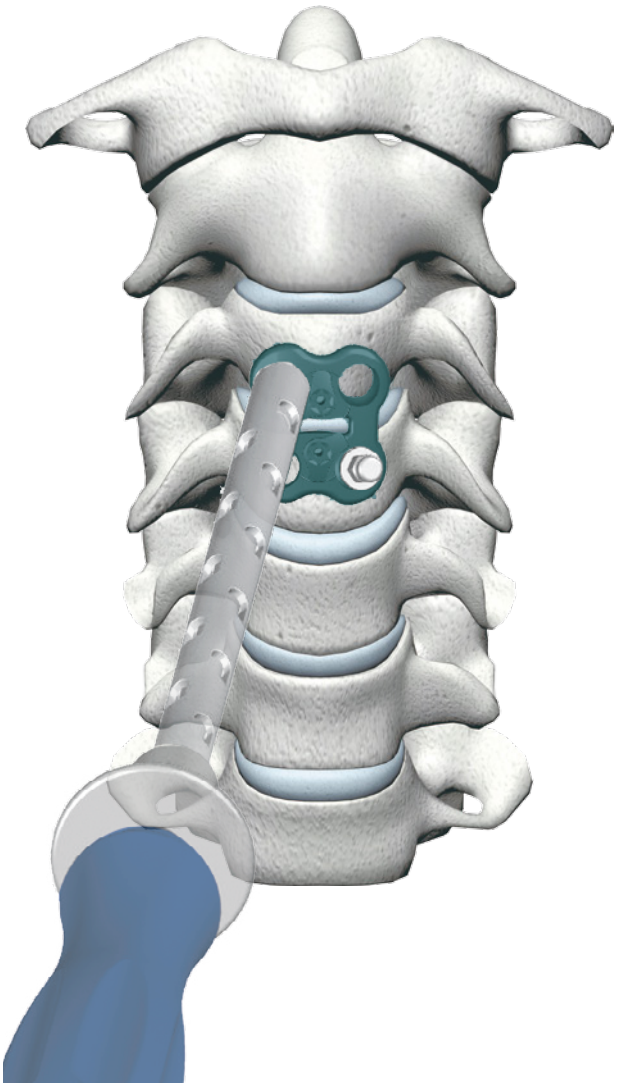


Figure 5

STEP 5: SCREW SELECTION

The Avem Anterior Cervical Plate System offers surgeons the versatility to place their screws at additional angulations into the vertebral bodies. The system offers both selftapping and self-drilling screws options. The system screw incorporates a dual thread screw pattern designed to maximize interface with cancellous bone.

Figure 6 below shows just a few options for screw placement.

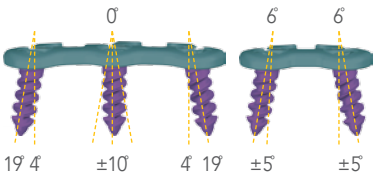


Figure 6

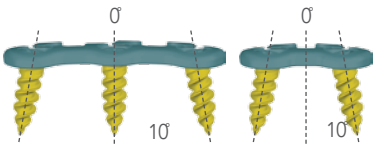


Figure 7

Figure 8

Using the Self-Constrained Aw

Once the plate is positioned and temporarily fixed to the vertebral bodies, place the tip of the Self-Constrained Awl in the screw bore and press it in the direction of the desired screw angle. The Self-Constrained Awl can protrude into the bone up to a depth of 8.5mm (Figure 9). To penetrate dense cortical bone, strike the handle of the Self-Constrained Awl with a mallet.

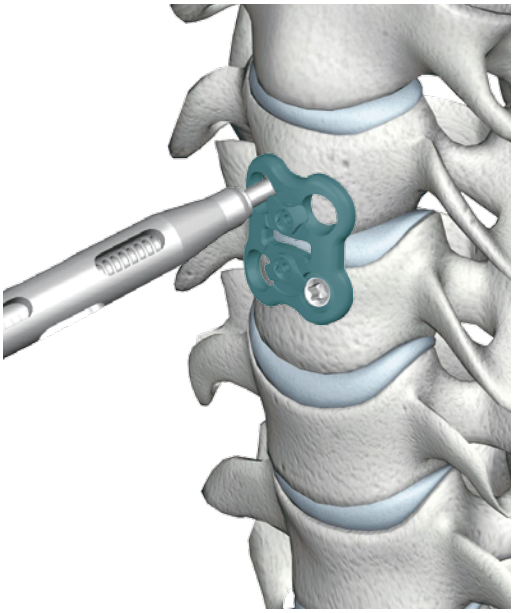


Figure 9

STEP 6: SCREW POSITIONING

- Attach the desired drill bit onto the AO I-Handle or power drill.
  Advance the drill bit through the drill guide until the shelf of the drill contacts the guide (Figure 10).
  The Avem Anterior Cervical Plate System provides both self-drilling and self-tapping screws.

- A 10 mm tap is provided should tapping be required.

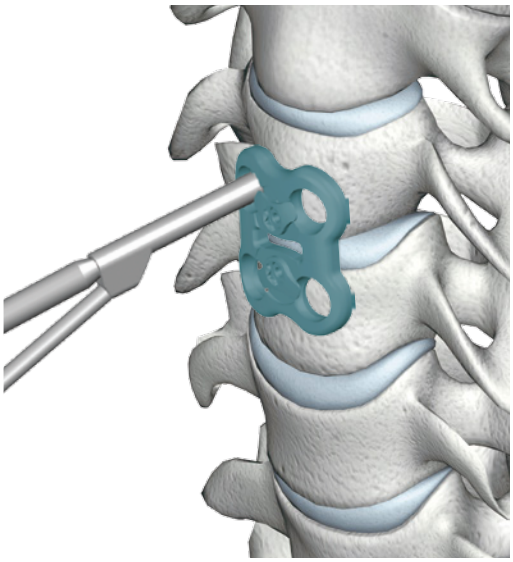


Figure 10

STEP 7: SCREW INSERTION

- Use the screw driver to pick up the appropriate bone screw, insert the screw tip into the previously prepared bone screw hole.

- Use fluoroscopic imaging to confirm the final trajectory of the screw and plate position before screws are fully tightened and secured with the CAP.

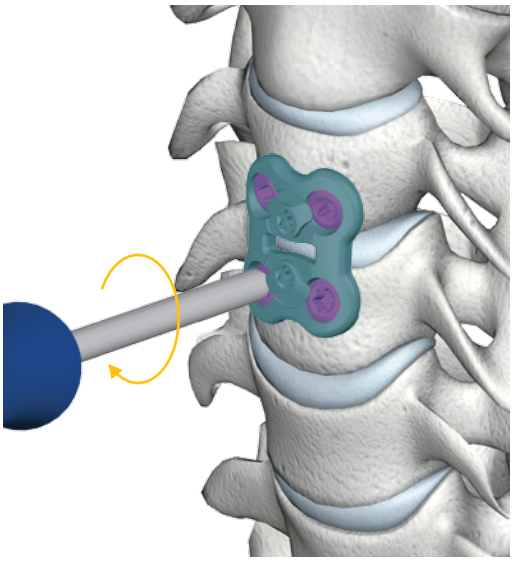


Figure 11

STEP 8: LOCKING THE CAPS

The Avem Anterior Cervical Plate System includes an attached locking CAP mechanism.

- Insert the tip of the CAP tightener shaft into the CAP ensuring that the screw driver is fully seated within the CAP.
- Rotate the CAP clockwise until the CAP is parallel with the vertebral body (Figure 13). Be careful to ensure that the CAP is not over turned, as damage may occur.

Lock Unlock

Figure 12

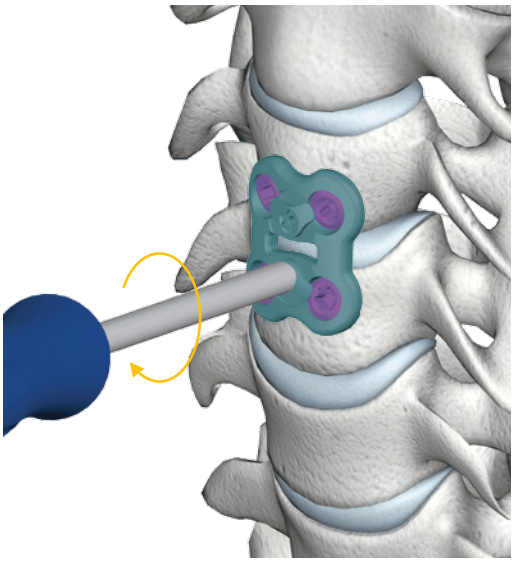


Figure 13

Optional Instrument : Double DTS

To attach the Double DTS Guide, begin with the guide off the distal end of the plate. Place one side of the guide in the side slot on the plate (Figure 14).

Next, twist the opposite side into position. Typically it is easier to attach the Double DTS Guide when downward pressure is maintained on the guide to keep contact between the guide and the plate.

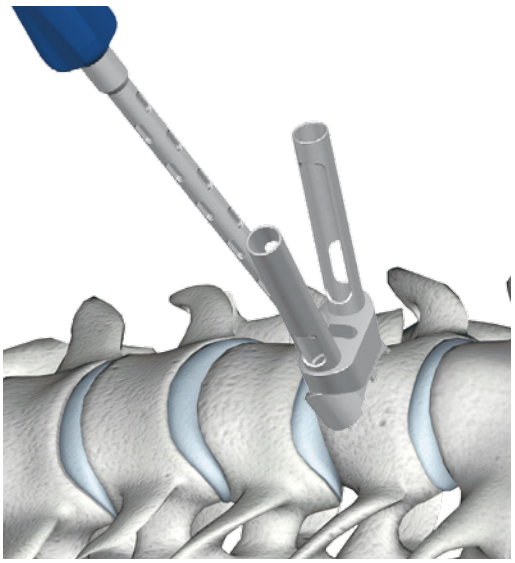


Figure 14

Removal Technique

- Items needed : Screw driver, Hexlobe screw Removal tool.
- Insert the tip of the CAP tightener shaft into the CAP ensuring that the screw driver is fully seated within the CAP.
- Rotate the CAP counter-clockwise until the CAP is parallel with the vertebral body (Figure 15). Be careful to ensure that the CAP is not over turned, as damage may occur.

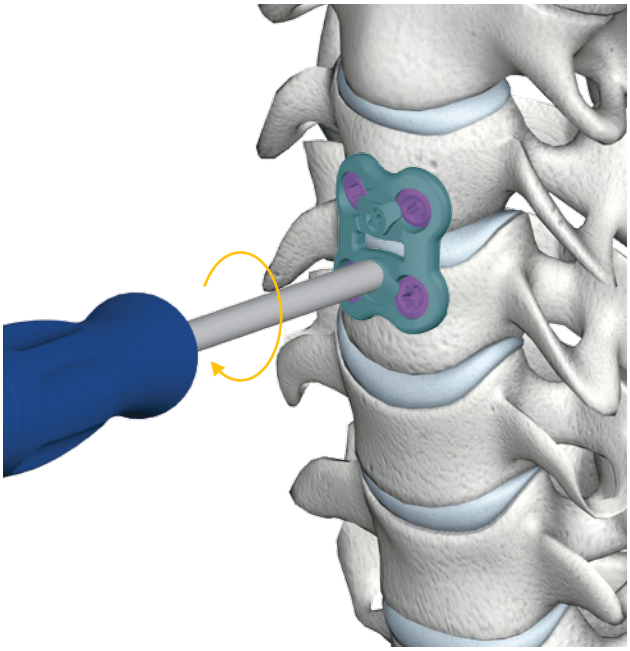


Figure 15

- Items needed : Screw driver, Hexlobe screw Removal tool.
- Insert the tip of the CAP tightener shaft into the CAP ensuring that the screw driver is fully seated within the CAP.
- Rotate the CAP counter-clockwise until the CAP is parallel with the vertebral body (Figure 16). Be careful to ensure that the CAP is not over turned, as damage may occur.

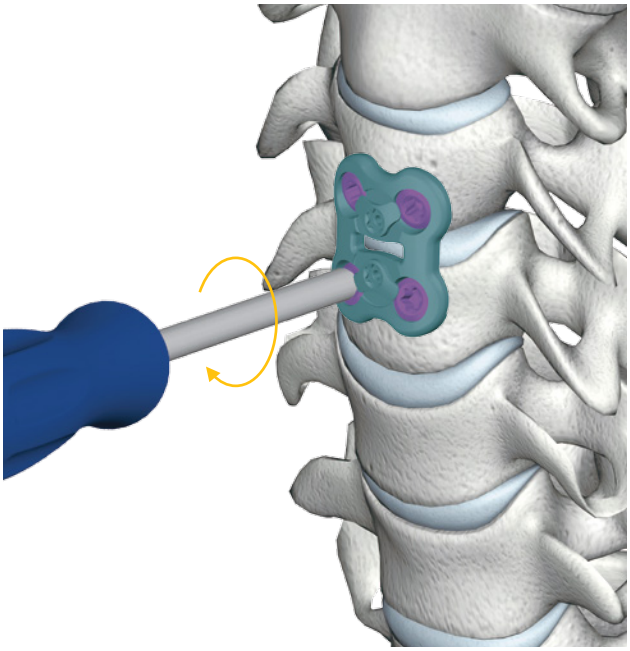


Figure 16

Instruments

1.5932.1106 One Surgical Avem Drill 10mm
1.5932.1107 One Surgical Avem Drill 12mm
1.5932.1108 One Surgical Avem Drill 14mm
1.5932.1109 One Surgical Avem Drill 16mm

1.5932.1111 One Surgical Avem Double DTS

1.5932.1112 One Surgical Avem Single DTS

1.5932.1113 One Surgical Avem Tap 10mm

Instruments

1.5932.1114 One Surgical Avem Plate Holder

1.5932.1115 One Surgical Avem Plate Bender

1.5932.1116 One Surgical Avem Hexlobe Screw Removal Tool

1.5932.1117 One Surgical Avem Temporary Fixation Pin

Instruments

1.5932.1118 One Surgical Avem Temporary Fixation Pin Inserter

1.5932.1119 One Surgical Avem Self Constrained Awl

1.5932.1121 One Surgical Avem Drill Guide-Fixed

1.5932.1122 One Surgical Avem Drill Guide-Variable

Instruments

1.5932.1123 One Surgical Avem Screw Driver

1.5932.1124 AO I-Handle

Warning and Cautions

WARNING

01. While the expected life of spinal implant components is difficult to estimate, its life span is finite. These components are made of foreign materials and placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors, these devices are affected and cannot be expected to withstand the activity level and loads of normal healthy bone.
02. Do not use this product other than its indication. Cannot be inserted other than indicated area and cervical vertebrae is not allowed.
03. The One Surgical Avem Anterior Cervical Plate System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended 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 Avem 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.
04. Never use a damaged, explanted implant or one which has been used erroneously when it has come into contact with tissues. The implant must be discarded.
05. This product is one time use only and can never be re-used in any occasions. Re-use of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time, and may result in premature rupture. While the device may appear to be undamaged, it may have small defects or internal stress patterns, as a result of the prior implantation or removal that could lead to fatigue failure. Additionally, please note that the removed implant has not been designed or validated so as to allow for decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process. The company accepts no responsibility for implants which have been reused.
06. Non-sterilized implants must be sterilized and decontaminated prior to surgical use as instructed by the manufacturer.
07. All instruments are delivered non-sterilized and therefore, must be cleaned, sterilized and decontaminated prior to surgical use as instructed by the manufacturer.
08. A wrong choice of implant size may cause damage to the product and may become the reason of unsuccessful surgery. Therefore, product's design and size should be selected after full consideration of patient's weight, amount of exercise, area of vertebral checked by X-ray, levels of implantation, compliance of the patient, and other patient conditions which may have an impact on the performance and results of this system. Please refer to "the choice of implant".
09. It cannot be used with other product without validation regarding safety and effectiveness. If it is used with other product, Solco Biomedical Co., Ltd do not take any responsibility.
10. Where material oversensitivity is suspected, appropriate tests must be made prior to material selection or implantation.
11. It is important for surgeon and medical staff to be well-informed of the following information and give it to patient before the procedure, in order to be warned of the potential consequences and ensure success of the surgical implantation:
- Clinical data show that patients who smoke tend to have less optimum bony consolidation, as well as patients who are undernourished, alcoholic, obese, or patients with drug abuse, muscle weakness or nerve paralysis.
- To aid bone healing it is important to limit use of nicotine and non-steroidal medicinal products (ex.: aspirin).
- The implanted device must not be subjected to exposure to unwanted forces such as mechanical vibrations. Consequently, the patient must be informed of limiting his or her physical activity (athletic and occupational), especially in the cases of lifting, twisting and crushing.
- Throughout the period of consolidation, the patient must follow the surgeon's instructions and recommendations.
- These implants do not present any known risk of interference with other medical equipment.
- Safety and compatibility of the device in the setting of magnetic resonance (imaging) have not been evaluated. No thermal test or test of migration has been performed on the device in this setting.
12. Spinal surgery is not recommended for patients with alcohol abuse, morbid obesity, poor bone and muscle quality and/or nerve paralysis.
13. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

CAUTION

01. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
02. The benefit of spinal fusions utilizing any intervertebral body fusion device has not been adequately established in patients with stable spines.
03. A condition of senility, mental illness, or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
04. Compliance with pre-operative and perioperative procedures, including knowledge of the surgical technique, as well as the proper selection and positioning of implants are important factors in success of use of the system by the surgeon. Knowledge and experience in spinal surgery are pre-requisites.
05. Physician note: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.
06. Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Also, patients who smoke or abuse alcohol are poor candidates for spinal fusion as someone who should be advised and warned of the consequences of the fact that an increased incidence of non-union has been reported with such patients.
07. A successful result is not always achieved in every surgical case due to many extenuating circumstances. This is especially true in spinal surgeries where other patient conditions or many extenuating circumstances may compromise the results.
08. Non-Sterilized implants must be placed on sterilization for use.
09. Never reuse the implant under any circumstances. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. Reuse can potentially compromise device performance and patient safety.
10. The compatibility needs to be verified before use with other product.
11. The products must be stored away from contact with metal or abrasive materials to prevent cracks or scratches. The product maybe damaged from loads due to scratches not visible with naked eyes.
12. The use of implants may interfere with the anatomical structure or physiological performance of the patient. It should be reviewed carefully about radiological diagnosis and its side effects before the procedure.
13. One Surgical Avem Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of One Surgical Avem Anterior Cervical Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
14. Without solid bone fusion, this device cannot be expected to support the cervical spine indefinitely and may fail due to bone-metal interface, metal or bone failure.
15. Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

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