VELOX™ ANTERIOR CERVICAL PLATE SYSTEM IMPLANTS

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

IMPORTANT NOTE TO OPERATING SURGEON

VELOX spinal implants, like any other temporary internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used, if a pseudo-arthrosis develops, or if patients have severe or multiple preoperative curves.

The surgeon may remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

DESCRIPTION

The VELOX Anterior Cervical Plate System consists of a variety of bone plates and screws. Fixation is provided by the insertion of bone screws through the openings at each end of the plate into the vertebral bodies of the cervical spine. Associated instruments are also available to facilitate the implantation of the device.

The VELOX Anterior Cervical Plate System implant components (plate and screws) are made from titanium alloy conforming to ASTM F136 specifications. The screw retaining rings are made of CoCr28Mo6 per ASTM F1537. Do not use any of the VELOX Anterior Cervical Plate System components with the components from any other system or manufacturer.

INDICATIONS

The VELOX Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e. fractures or dislocations), tumors, deformity, pseudarthrosis, failed previous fusion, spinal stenosis.

WARNING: The VELOX Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

The VELOX Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. The VELOX Anterior Cervical Plate System has not been tested for heating or migration in the MR environment.

STERILIZATION

Implants and instruments of the VELOX Anterior Cervical Plate System are supplied clean and not sterile. All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Instructions for cleaning and sterilization of VELOX instruments can be found in SpineCraft publication # RG-0032-1 and can be obtained by contacting the company. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the set of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	30 Minutes

Wrap: The wrap should be FDA cleared for the proposed cycle specifications.

Or

Rigid Sterilization Container: The following Aesculap sterilization rigid container components are validated for use:

- Aesculap Extra-Long Container, Perforated Bottom, 5½ -inch (P/N JN443)
- Aesculap Extra-Long Container, Perforated Bottom, 8-inch (P/N JN445)
- Aesculap Extra-Long Container, Lid with Retention Plates (P/N JK490)
- Aesculap Single use 7 ½" diameter filter with indicator dot (P/N US751)
- Aesculap Single use 7 ½" diameter filter (P/N US994)

Monitor every load with a PCD containing a BI and a Class 5 integrating indicator.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
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 allergy or intolerance.
10. Any case not needing a bone graft and fusion or where fracture healing is not required.
11. Any case requiring the mixing of metals from different components.
12. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
13. Any case not described in the Indications.
14. Any patient unwilling to cooperate with the post-operative instructions.
15. Any time implant utilization would interfere with anatomical structures or expected physiological performance.
16. Any condition not described in the Indications for Use.

WARNINGS, PRECAUTIONS, AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

WARNINGS

1. **CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT**. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. **IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.** Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. **MIXING METALS CAN CAUSE CORROSION**. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerates the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, etc., which come into contact with other metal objects, must be made from like or compatible metals.

4. **PATIENT SELECTION**. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

   A. **The patient's occupation or activity**. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

   B. **A condition of senility, mental illness, alcoholism, or drug abuse**. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

   C. **Certain degenerative diseases.** In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary remedy.

   D. **Foreign body sensitivity**. The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction.

Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

E. **Smoking.** Patients who smoke have been observed to experience higher rates of pseudo-arthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

PRECAUTIONS

1. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. Reusing an implant can potentially cause cross contamination. It is advised to utilize new implant of current design.

2. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT**. Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

3. **CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING**. If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

4. **ADEQUATELY INSTRUCT THE PATIENT**. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

5. **CORRECT PLACEMENT OF ANTERIOR SPINAL IMPLANT.** Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurologic damage with the use of this product. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants or if pulsatile erosion of the vessels occurs because of close apposition of the implants.

6. **IMPLANTS FATIGUE**. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

7. **PREVIOUS SPINAL SURGERY.** Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

POSSIBLE ADVERSE EFFECTS

1. Bending or fracture of implant.
2. Loosening of the implant.
3. Metal sensitivity, or allergic reaction to a foreign body.
4. Infection, early or late.
5. Nonunion, delayed union.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
9. Bursitis.
10. Paralysis.
11. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
12. Death.
13. Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
14. Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
15. Damage to lymphatic vessels and/or lymphatic fluid exudation.
16. Spinal cord impingement or damage.
17. Fracture of bony structures.
18. Degenerative changes or instability in segments adjacent to fused vertebral levels.

LIMITED WARRANTY AND DISCLAIMER: THE VELOX ANTERIOR CERVICAL PLATE SYSTEM PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION AND THE DATE OF CONSULTATION, CONTACT SPINECRAFT FOR CURRENT INFORMATION at: +1 630-920-7300.

SURGICAL TECHNIQUE MANUAL CAN BE OBTAINED BY CONTACTING SPINECRAFT CUSTOMER SERVICE at +1 630-920-7300. ALSO, IT COULD BE DOWNLOADED DIRECTLY FROM THE COMPANY WEBSITE USING THE SURGEON LOG-IN.

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