ENGLISH

CTL MEDICAL
4550 EXCEL PARKWAY, STE 300
ADDISON, TX 75001 USA
PHONE: 214-545-5820
WWW.CTLMED.COM

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

Single Use Only
DO NOT RESTERILIZE

VALEO® SPACER IMPLANT SYSTEMS

The VALEO Spacer is manufactured from MC²® silicon nitride, a ceramic material.
As with all orthopedic implants, do not re-use these implants.

The Valeo II Interbody Fusion Device has not been evaluated for safety and compatibility in the MR environment. The Valeo II Interbody Fusion Device has not been tested for heating or migration in the MR environment.

Indications

The Valeo Spacer System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. The device must be used with additional anterior or posterior instrumentation to augment stability.

The VALEO C is intended for use at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The VALEO C is to be used in patients who have had six weeks of non-operative treatment.

The VALEO TL, PL, OL, AL are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The VALEO TL, PL, OL, AL is to be used in patients who have had six months of non-operative treatment.

Contraindications

General 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 presence of tumors or congenital abnormalities, 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 relativecontraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
9. SUSPECTED OR DOCUMENTED METAL ALLERGY or intolerance.
10. ANY CASE NEEDING TO MIX METALS from different components.
11. ANY PATIENT HAVING INADEQUATE TISSUE COVERAGE over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
12. ANY CASE NOT DESCRIBED in the indications.
13. ANY PATIENT UNWILLING TO CO-OPERATE with postoperative instructions.
14. THESE DEVICES MUST NOT BE USED FOR PEDIATRIC CASES, nor where the patient still has general skeletal growth. Contraindications of this device are consistent with those of other spinal systems.

Possible Adverse Effects

All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes, but is not limited to:
1. EARLY OR LATE LOOSENING of the components. Implant migration.
2. DISASSEMBLY, BENDING, AND/OR BREAKAGE of any or all of the components.
3. FOREIGN BODY (ALLERGIC) REACTION to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
4. INFECTION.
5. DURAL TEARS, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
6. TISSUE OR NERVE DAMAGE, irrigation, and/or pain caused by improper positioning and placement of implants or instruments.
7. LOSS OF NEUROLOGIC FUNCTION, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, presthesia, appearance or radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss and/or spasms.
8. CAUDA EQUINA SYNDROME, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
9. SCAR FORMATION possibly causing neurological compromise around nerves and/or pain.
10. URINARY RETENTION or loss of bladder control or other types of urological system compromise.
11. BONE Loss or decrease in bone density, possibly caused by stress shielding.
12. SUBSIDENCE of the device into vertebral body(ies).
13. POSTOPERATIVE CHANGE IN SPINAL CURVATURE, loss of correction, height, and/or reduction.
14. 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.
15. NON-UNION (or pseudoarthrosis). Delayed union. Mal-union.
16. FRACTURE, MICROFRACTURE, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the bone graft, or at the bone graft harvest site-at, above, and/or below the level of surgery.
17. GRAFT DONOR SITE COMPLICATIONS including pain, fracture, infection, or wound healing problems.
18. HERNIATED NUCLEUS PULPOSUS, disc disruption or degeneration at, above, or below the level of surgery.
19. ILEUS, GASTRITIS, bowel obstruction or other types of gastrointestinal system compromise.
20. HEMORRHAGE, HEMATOMA, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
21. REPRODUCTIVE SYSTEM COMPROMISE, including sterility, loss of consortium, and sexual dysfunction.
22. DEVELOPMENT OF RESPIRATORY PROBLEMS, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. CHANGE IN MENTAL STATUS.
24. DEATH.

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

Warnings and Precautions

A SUCCESSFUL RESULT IS NOT ALWAYS ACHIEVED in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. This device system is not intended to be the sole means of spinal support. THE VALEO SPACER SYSTEM MUST BE USED WITH ADDITIONAL ANTERIOR OR POSTERIOR INSTRUMENTATION TO AUGMENT STABILITY. Use of this product without an autograft may not be successful. 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.

Consider preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant and good reduction prior to surgery. Only perform installation and positional adjustment of implants with special equipment and instruments specific to these devices. Do not use other instruments unless specifically recommended by CTL Medical because other instruments may be incompatible.

NEVER REUSE AN INTERNAL FIXATION DEVICE UNDER ANY CIRCUMSTANCES. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage to the connection mechanism will reduce instrument stability.

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, and/or alcohol abuse patients are also poor candidates for spine fusion.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

Preoperative

The selection of the proper size, shape and design of the implant for each patient is crucial to planning the success of the procedure. Ceramic implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.
1. USE CARE IN HANDLING and storing these components. Do not scratch or damage them. Protect implants and instruments during storage especially from corrosive environments.
2. SINCE MECHANICAL PARTS ARE INVOLVED, be familiar with the various components before using the equipment and personally assemble the devices to verify that all parts and necessary instruments are present before surgery.
3. DETERMINE THE TYPE OF CONSTRUCT to be assembled for the case prior to surgery. Have an adequate inventory of implant sizes available at the time of surgery, including sizes larger and smaller than those expected to be used.
4. UNLESS PACKAGED STERILE, clean and sterilize all parts before use. Have additional sterile components available in case of an unexpected need.

Intraoperative

1. CAREFULLY FOLLOW THE INSTRUCTIONS in any available applicable surgical technique manual.
2. AT ALL TIMES, USE EXTREME CAUTION AROUND THE SPINAL CORD and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. BREAKAGE, SLIPPAGE, OR MISUSE OF INSTRUMENTS or implant components may cause injury to the patient or operative personnel.
4. TO ENSURE PROPER FUSION below and around the location of the instrumentation, use a bone graft. When using the VALEO Spacer, use grafts containing autogenous bone.
5. DO NOT USE BONE CEMENT since it will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

Postoperative

Postoperative directions and warnings to the patient and patient compliance are extremely important.

1. GIVE THE PATIENT DETAILED INSTRUCTIONS on the device's use and limitations. If partial weight bearing is recommended or required prior to firm bony union, warn the patient that device bending, loosening, or breakage can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation maybe increased if the patient is active or if the patient is debilitated, demented, or otherwise unable to use crutches or other weight supporting devices. Warn the patient to avoid falls or sudden jolts in spinal position.
2. FOR OPTIMAL SURGICAL RESULTS, do not expose the patient or device to mechanical vibrations that may loosen the device construct. Warn the patient of this possibility, and instruct the patient to limit physical activities, especially lifting and twisting motions and any type of sport participation. Advise the patient not to smoke or consume excess alcohol during the bone graft healing process.
3. ADVISE THE PATIENT NOT TO BEND at the point of spinal fusion, and teach the patient to compensate for this permanent physical restriction in body motion.
4. FAILURE TO IMMOBILIZE a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By fatigue, these stresses can cause eventual loosening, or breakage of the device. It is important that union immobilization is established and confirmed by roentgenographic examination. Where there is a non-union, or if the device loosens and/or breaks, the device should be revised immediately before serious injury occurs.

Packaging

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, check all sets for completeness and all components for lack of damage prior to use. Do not use damaged packages or products; return them to CTL Medical Corporation. Remove all packaging prior to sterilization.

Cleaning and Decontamination

Clean all instruments using established hospital methods before sterilization and introduction into a sterile surgical field. Decontaminate and clean all instruments that have been previously taken into a sterile surgical field using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and disinfecting of instruments can be performed with alkali aldehyde-free solvents at higher temperatures. Cleaning and decontamination can include the use of neutral cleaners followed by deionized water rinse.
NOTE: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; do not use these solutions. Certain instruments may require dismantling before cleaning. Treat all products with care. Improper use or handling may lead to damage and possible improper device function.

Refer to the Valeo Surgical Instrument Sets Care, Cleaning and Sterilization Instructions for Use for detailed information.

Sterilization

STERILE R

Unless otherwise indicated, all components have been sterilized by a minimum of 25 kGy (2.5 MRads) of gamma irradiation and are supplied packaged in protective trays or pouches. This sterilization is validated by AAMI TIR33:2005 Sterilization of Healthcare Products – Requirements for Validation and Routine Control – Radiation Sterilization and Sterilization of Healthcare Products – Radiation Sterilization-Substantiation of 25 kGy as a sterilization dose - Method VDmax to an SAL of 10-6. Inspect packages for punctures and other damage prior to surgery.

CTL MEDICAL DOES NOT RECOMMEND RESTERILIZATION OF IMPLANTABLE MEDICAL DEVICES.

Further Information

Surgical instructions on the use of this device are available in the Surgical Technique Guide. Please contact your sales representative or CTL Medical directly at the phone number listed above. In case of complaint, or for supplementary information, or further directions for use of this system, please see Amedica's address above.

CTL Medical Corporation. #825103 Rev. M