ENGLISH

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	Manufacturer		
	Do not use if package is damaged	QTY	Quantity
	Single use only	REF	Catalog number
	Consult instructions for use	LOT	Batch code
℞ ONLY	Prescription use only		
	Use by date	STERILE R	Sterilized product using irradiation

Manufactured by CTL Medical Corporation (d/b/a: CTL Amedica)
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VALEO/VALEO II™ INTERBODY FUSION DEVICES

The implants of the Valeo / Valeo II Interbody Fusion Devices are manufactured from silicon nitride, a ceramic material. Valeo / Valeo II Interbody Fusion Devices should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Refer to the Valeo / Valeo II Interbody Fusion Devices Surgical Technique Manual for complete Instructions for use. Valeo / Valeo II Interbody Fusion Devices have not been evaluated for safety and compatibility in the MR environment. The Valeo / Valeo II has not been tested for heating or migration in the MR environment.

Indications

Valeo / Valeo II Interbody Fusion Devices - Cervical are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level or two contiguous levels.

DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Valeo / Valeo II Interbody Fusion Devices-Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach from the C2-C3 disc space to C7-T1 disc space using autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Valeo / Valeo II Interbody Fusion Devices-Cervical are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Valeo / Valeo II Interbody Fusion Devices-Lumbar are indicated for use with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s).

Valeo / Valeo II Interbody Fusion Devices-Lumbar are intended to be used with supplemental spinal fixation systems. Patients should be skeletally mature and have six months of non-operative therapy prior to treatment with an intervertebral cage.

Contraindications

1. Valeo / Valeo II Interbody Fusion Devices are contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, drug/alcohol abuse, mental illness, general neurologic conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity and patients who are unwilling to restrict activities or follow medical advice.
2. Biological factors such as smoking, use of nonsteroidal antiinflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. This device is not intended for use except as indicated.

Possible Adverse Effects

Potential adverse events include, but are not limited to pseudoarthrosis; loosening, bending, cracking or fracture of components, or loss of fixation in the bone with possible neurologic damage, usually attributable to pseudoarthrosis, insufficient bone stock, excessive activity or lifting, or one or more of the factors listed in Contraindications, or Warnings and Precautions; infections possibly requiring removal of devices; palpable components, painful bursa, and/or pressure necrosis; and allergies, and other reactions to device materials which, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.

Warnings and Precautions

1. 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.
2. Mixing titanium and stainless implant components should be avoided.
3. The use of surgical implants has given the surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgery. However, these implants are intended only to assist bony healing and are not intended to replace normal body structures. Vertebral interbody fusion devices are used to support and maintain alignment while normal healing occurs. The size and shape of bones and soft tissue place limitations on the size and strength of implants.
4. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and material aspects of surgical implants. Postoperative care is extremely important. The patient should be warned that noncompliance with postoperative instructions could lead to breakage of the implant and/or possibly migration requiring revision surgery to remove the device.
5. There are specific adverse effects, warnings and precautions, which should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to internal fixation devices. General surgical risks should also be explained to the patient prior to surgery.
6. Valeo II Interbody Fusion Devices are used in spinal arthrodesis, or fusion, a surgical procedure to fuse together two or more spinal vertebrae to provide stability to an otherwise unstable spinal column. For optimum results, careful preoperative diagnosis and planning, meticulous surgical technique, and extended postoperative care are essential. It is important that both patient and doctor be fully aware of all possible risks and complications involved in such a procedure.
7. Valeo II Interbody Fusion Devices consist of hollow tube structures manufactured from medical grade silicon nitride and are used as vertebral interbody devices.
8. Prior to use, the physician should be trained in the surgical procedure recommended for use of these devices.

Preoperative

1. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, and fracture of the vertebra, neurological injury, and vascular or visceral injury.
2. Correct selection of the implant is extremely important. The potential for successful healing 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 presents limitations on the size and strength of implants.
3. Use care in handling and storage of implant components. Cutting, bending, or scratching the surface of components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided where possible. These, in turn, may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Special protection of implants and instruments during storage is recommended when exposed to corrosive environments such as moisture, salt air, etc. Inspection should be made to determine if components have been damaged.
4. Patient conditions and/or predispositions such as those previously addressed, should be avoided.
5. An adequate inventory of implant sizes should be available at the time of surgery.
6. Allergies and other reactions to device materials although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
7. Special surgical instruments are required to perform this surgery. Review of the use and handling of these instruments is very important.
8. Before the initial experience, we recommend that the surgeon critically review all available information and consult with other surgeons having experience with the device, and/or attend a training course.

Operative

1. The primary goal of this surgery is to arthrodese selected vertebral bodies. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. The placement of the vertebral interbody fusion implants should be checked radiographically prior to final tightening of the construct.
3. Care should be taken when positioning the implants to avoid neurological damage.

Postoperative

1. Physicians should instruct the patient to contact the surgeon in the event of significant increase in pain which may indicate a device performance issue. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing. This is particularly important should the device be used to treat an unstable fracture. The patient must be made aware of the limitations of the implant and that physical activity and load bearing have been implicated in premature loosening, bending, or fracture of internal fixation device. An active, debilitated, or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.
2. Implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a bone has healed. If an implant remains implanted after complete healing, it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.
3. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and/or early revision considered.
4. Surgical implants must never be reused. An explanted implant should never be re-implanted. Even though the device appears undamaged, it may have small imperfections and internal stress patterns which may lead to early breakage.

Packaging

Packages for each of the components should be intact upon receipt. Damaged packages or products should not be used, and should be returned to CTL Medical Corporation.

Cleaning and Decontamination

All instruments must first be cleaned using neutral cleaners before sterilization and introduction into a surgical field or (if applicable) return the product to CTL Medical Corporation . Cleaning and disinfecting of instruments can be performed with aldehdye-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.
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 health care 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 MEDCIAL DOES NOT RECOMMEND RESTERILIZATION OF IMPLANTABLE MEDICAL DEVICES.

Product Complaints

Any health care professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or CTL Medical Corporation.

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 Corporation 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 CTL Medical Corporation address above.