aprevo® anterior and lateral lumbar interbody system

Instructions for Use

DESCRIPTION

The aprevo® anterior and lateral lumbar interbody system is designed to stabilize the lumbar spinal column and facilitate fusion. The personalized aprevo® devices incorporate patient-specific features and include an aperture intended for the packing of bone graft. The aprevo® devices are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001, and the fixation screws are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The aprevo® devices are provided sterile and fabricated in a variety of heights, widths, and anterior-posterior lengths and may incorporate lordotic and/or coronal angulation.

INTENDED USE

The aprevo® anterior and lateral lumbar interbody system is intended to stabilize a spinal segment and facilitate fusion using bone graft.

INDICATIONS FOR USE

aprevo® ALIF and LLIF interbody systems
The aprevo® ALIF and LLIF interbody systems are intended for interbody fusion in skeletally mature patients and are to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The aprevo® ALIF and LLIF interbody systems are indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had six months of non-operative treatment. The devices are intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These devices may be implanted via a variety of open or minimally invasive approaches. These approaches may include anterior lumbar interbody fusion or lateral lumbar interbody fusion.

The aprevo® ALIF and LLIF interbody systems are indicated for use at one or more levels of the lumbosacral spine as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six months of non-operative treatment. The aprevo® ALIF and LLIF interbody systems are to be filled with autograft bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems). These devices may be implanted via a variety of open or minimally invasive approaches.

aprevo® ALIF-X interbody system
The aprevo® ALIF-X interbody system is intended for interbody fusion in skeletally mature patients. The aprevo® ALIF-X interbody system is indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had six months of non-operative treatment. The device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous bone and/or corticocancellous bone and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The device may be implanted via an open or minimally invasive approach.

The aprevo® ALIF-X interbody system is indicated for use at one or more levels of the lumbosacral spine as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis, kyphosis, or sagittal), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. The aprevo® ALIF-X interbody system is intended for standalone use at one or two levels of the spine when used with the screws that accompany the implant and with implants less than or equal to 20° of lordosis. At more than two levels or with implants greater than 20° of lordosis, the aprevo® ALIF-X interbody system is intended to be used with the screws that accompany the implant and with supplemental fixation. When used at more than one level in patients with degenerative scoliosis and/or sagittal deformity, the aprevo® ALIF-X interbody system must be used with the screws that accompany the implant and with supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine. These patients should be skeletally mature and have had at least six months of non-operative treatment. The device is to be filled with autograft bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. The device may be implanted via an open or minimally invasive approach.

Caution: For product sold in the USA: Federal Law (USA) restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS

Contraindications for the aprevo® device include, but are not limited to:

- Presence of fever, infection, or inflammation (systemic or localized)
- Morbid obesity
- Pregnancy
- Mental illness or drug abuse
- Severe osteopenia (or any other medical or surgical condition) that would preclude potential benefits of implants
- Suspected or documented allergy or intolerance to metals
- Patients unwilling or unable to follow instructions regarding post-operative care or limitations
- Diffuse multilevel neoplastic disease such that no adjacent normal segments exist for engagement of instrumentation
- Any case not listed in the indications

RELATIVE CONTRAINDICATIONS

- Osteoporosis
- Smoking
- Malnutrition
- Anemia
- Chronic hypoxemia
- Severe cardiopulmonary disease
- Severe depression/psychosocial issues
- Secondary gain issues

WARNINGS

The aprevo® device is designed as a patient-specific permanent implant and must only be used in the patient for whom it was designed. Only use the aprevo® device if the patient specific ID markings on the sterile package match the identification of the patient. The aprevo® device is supplied STERILE and should not be re-sterilized.

Do not use if package is opened or damaged or if expiration date has passed.

Large lordotic angles, such as those ≥20°, may increase the risk of migration in the anterior direction when the anterior longitudinal ligament (ALL) has been resected. Hyperlordotic anterior interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation. Hyperlordotic lateral interbody devices (≥20° lordosis) must be used with at least lateral supplemental fixation and anterior supplemental fixation. In addition, it is recommended that anterior supplemental fixation be used with anterior interbody devices regardless of lordotic angle.

The aprevo® device may become loose or break if subjected to increased loading, especially in the condition of delayed union or non-union. The implant's longevity can be affected by the patient's weight, activity level, and adherence to load-bearing instructions. Delayed union or non-union can result in loads on the implant over time that are higher than expected, increasing the risk of implant breakage. The patient should be made aware of the risks of implant failure.

Correct selection of the implant is extremely important. A properly sized device will provide the best stability of the spinal column and distribution of the intervertebral load across the vertebral endplates. The strength of a properly sized device, however, is limited by the size and shape constraints of the intervertebral space, and any such implant cannot be expected to withstand activity levels equal to those placed on normal healthy bone.

Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include device component fracture, loss of fixation, pseudoarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and vascular or visceral injury.

These warnings do not include all of the adverse effects that could occur with implantation of the aprevo® device or with any surgery. Patients should be informed of the risks associated with spinal surgery, general surgery, and the use of general anesthesia prior to surgery. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

PRECAUTIONS

The implantation of the aprevo® device should be performed only by experienced spinal surgeons with specific training in the use of this device, due to the technically demanding nature of the procedure and the potential for serious injury to the patient.

The aprevo® device is designed to support physiologic loads. Damage to the device from excessive forces or torque from the insertion instruments can cause defects in the device that can lead to misalignment or breakage and should be avoided. Do not implant any device that has fractured or has visible cracks, surface imperfections, or other damage.

The patient should be adequately informed about the advantages, disadvantages, and limitations of the aprevo® device and any supplemental internal fixation devices that may be used. The patient should be encouraged to ambulate as soon as possible following surgery, while limiting lifting and twisting motions and any type of sports activities until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend, or break if excessive demands are placed on it, especially if the bone has not completely healed. Implants displaced or damaged by improper activities may experience implant migration and subsequent damage to nerves or blood vessels.

Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the intervertebral body fusion device.

The aprevo® device 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 the aprevo® device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

The removal of supplemental fixation following completion of its intended use should be carefully considered by the surgeon. While not removing the supplemental fixation eliminates the risk associated with this additional surgery, leaving the implants in place could result in complications that include, but are not limited to:

- Risk of additional injury from post-operative trauma
- Bending, loosening, or breakage of the fixation implant
- Possible increased risk of infection
- Pain or discomfort associated with the fixation implant
- Bone loss or reduced bone healing due to stress shielding

POSSIBLE ADVERSE EFFECTS

Pre-operatively, the patient should be made aware of the possible adverse effects of spinal surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

- Bending or fracture of the implant
- Loosening or movement of the implant
- Implant material sensitivity or allergic reaction to a foreign body
- Infection, early or late
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma or presence of the device
- Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paresthesia
- Vascular damage could result in catastrophic or fatal bleeding
- Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later post-operative period
- 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
- Bursitis
- Spinal cord impingement or damage
- Fracture of bony structures
- Reflex sympathetic dystrophy
- Degenerative changes or instability in segments adjacent to fused vertebral levels
- Paralysis
- Death

DIRECTIONS FOR USE

The aprevo® device and associated screws and instruments are provided sterile. The sterilization method used is indicated on the device packaging label by one of the sterile symbols shown in the SYMBOLS GLOSSARY section.

Before using the aprevo® device for the first time, the surgeon should be thoroughly familiar with the aprevo® Surgical Technique Guide (available upon request) as well as the functionality and assembly of the device. Lack of experience or expertise with these implants may result in complications.

The aprevo® personalized device is fabricated to match a patient-specific pre-operative plan that is developed using the patient's radiological images. The patient-specific aprevo® device should not be used past the expiration date on the label or if the anatomy or condition of the intervertebral space has changed since the radiological images were acquired.

POST-OPERATIVE PATIENT CARE

Post-operative external immobilization (e.g., bracing or casting) is recommended, at the surgeon's discretion. The patient should be encouraged to ambulate as soon as possible following surgery, while limiting lifting and twisting motions and any type of sports activities until the bone is healed.

CUSTOMER SERVICE

For further information regarding the aprevo® device, or for a copy of the aprevo® Surgical Technique Guide, please contact Carlsmed, Inc. or your local aprevo® device distributor.

Carlsmed, Inc.
1800 Aston Avenue Suite 100
Carlsbad, California 92008
(760) 766-1923

SYMBOLS GLOSSARY

	Manufacturer		Use-by date		Consult instructions for use
Rx ONLY	Prescription only		Do not re-use		Single sterile barrier system with protective packaging inside
REF	Catalogue number		Do not resterilize	STERILE R	Sterilized using irradiation
LOT	Lot number		Do not use if package is damaged and consult instructions for use	STERILE	Sterilized using steam heat