aprevo® TLIF-C Articulating System

Instructions for Use

DESCRIPTION

The aprevo® TLIF-C Articulating System devices are designed to stabilize the lumbar spinal column and facilitate fusion. The personalized aprevo® devices incorporate patient-specific features to allow the surgeon to tailor the deformity correction to the individual needs of the patient. The aprevo® TLIF-C Articulating devices are made from Titanium Alloy (Ti-6Al-4V) and have a cavity intended for the packing of bone graft. The aprevo® TLIF-C Articulating devices are fabricated in a variety of heights, widths and anterior-posterior (A-P) lengths and may incorporate lordotic and/or coronal angulation.

INTENDED USE

The aprevo® TLIF-C Articulating System devices are intended to stabilize a spinal segment to facilitate fusion using bone graft.

INDICATIONS FOR USE

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

The aprevo® TLIF-C Articulating System is intended for interbody fusion in skeletally mature patients and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The aprevo® TLIF-C Articulating 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 and/or cortico-cancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches.

The aprevo® TLIF-C Articulating 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 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 (6) months of non-operative treatment. aprevo® TLIF-C Articulating System devices are to be filled with autograft bone and/or allogenic bone graft composed 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 implants may be implanted via a variety of open or minimally invasive approaches.

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) which 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
- Systemic infection
- 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.

The aprevo® device may become loose or break if subjected to increased loading, especially in the condition of delayed union or nonunion. The implant's longevity can be affected by the patient's weight, activity level, and adherence to load-bearing instructions. Delayed union or nonunion 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 which could occur with implantation of the aprevo® device or of any surgery. Patients should be informed of the risks associated with spinal surgery, general surgery and the use of general anesthesia. 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:

1. Bending or fracture of the implant. Loosening or movement of the implant
2. Implant material sensitivity, or allergic reaction to a foreign body
3. Infection, early or late
4. Decrease in bone density due to stress shielding
5. Pain, discomfort, or abnormal sensations due to the presence of the device
6. Nerve damage due to surgical trauma or presence of the device
7. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paresthesia
8. Vascular damage could result in catastrophic or fatal bleeding
9. Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period

10. Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis
11. Bursitis
12. Spinal cord impingement or damage
13. Fracture of bony structures
14. Reflex sympathetic dystrophy
15. Degenerative changes or instability in segments adjacent to fused vertebral levels
16. Paralysis
17. Death

DIRECTIONS FOR USE

The devices are provided sterile. The sterilization method used is indicated on the device packaging label by one of the sterile symbols below.

The aprevo® implant is provided sterile and requires no further preparation before use. The aprevo® implant has been sterilized by Gamma Irradiation.

An insertion instrument is provided sterile and requires no further preparation before use. The aprevo® insertion instrument has been sterilized by Gamma Irradiation.

The aprevo® implant is provided sterile and requires no further preparation before use. The aprevo® implant has been sterilized by Steam Heat.

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 devices are 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

Postoperative 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.

STORAGE

Sterile packaged implants should be stored at ambient temperatures in a clean dry area that prevents damage to the implant packaging.

CUSTOMER SERVICE

For further information regarding the aprevo® device, please contact Carlsmed, Inc. or your local device distributor.

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

SYMBOLS

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