ANTERALIGN™ LS COVERPLATE SYSTEM

PACKAGE INSERT

℞

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

DESCRIPTION OF THE MEDICAL DEVICE

The Anteralign™ LS coverplate System consists of a coverplate with a locking screw and an integrated locking mechanism. All implant components are manufactured from titanium alloy conforming to ASTM F136. The Anteralign™ LS coverplate may only be used with Medtronic's Anteralign™ LS Spinal System. The coverplate an optional device for use with Medtronic's Anteralign™ LS Spinal System.

No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

INDICATIONS FOR USE

When used with Anteralign™ LS Spinal System the Anteralign™ LS coverplate and cage is only intended to be used according to the indications of Medtronic's Anteralign™ LS Spinal System.

Anteralign™ LS Spinal System Indications for Use

The Anteralign™ LS Spinal System is intended to be used in spinal fusion procedures on skeletally mature patients with symptomatic Degenerative Disc Disease (DDD, defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis, at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. These patients should have had six months of nonoperative treatment prior to treatment with this device. Additionally, the Anteralign™ LS Spinal System and optional Anteralign™ LS Coverplate can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Anteralign™ LS interbody cage may be used as a stand-alone device or in conjunction with supplemental fixation. The Anteralign LS™ interbody fusion Device e may be inserted via minimally invasive or open anterior or oblique approach at one or two contiguous levels from L2 to S1. These approaches include anterior and oblique. When used as a stand-alone device, the Anteralign™ LS cage must be used with 3 screws with devices that have standard lordosis (≤16°). If the physician chooses to use less than 3 screws or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. When used in patients as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity conditions, additional supplemental fixation (e.g. posterior fixation) must be used. Additionally, cages with lordosis angles 16° or greater are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation).

INTENDED USE

The Anteralign™ LS coverplate System is an optional device intended to be used with the Anteralign™ LS Spinal System. When used, the Anteralign™ LS Spinal System and Anteralign™ coverplate LS System stabilize and promote bone fusion between two adjacent lumbar vertebral bodies during the normal healing process following surgical correction of disorders of the spine. The Anteralign™ Spinal System is intended for in vivo use. The product should be implanted only by a physician thoroughly knowledgeable in the implant's material and surgical aspects and instructed as to its mechanical and material applications and limitations.

MATERIAL

All implant components are manufactured from titanium alloy conforming to ASTM F136.

CONTRAINDICATIONS

This device is not intended for cervical spine use. Contraindications include:

- Cases where there is translational instability (spondylolisthesis of any grade or retrolisthesis) at the level treated unless posterior supplemental fixation is used to augment stability.
- Cases where posterior elements were removed such that it introduces instability at the level(s) treated unless posterior supplemental fixation is used to augment stability.
- Severe osteoporosis.
- Patients having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Infection local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials.
- Cases not needing a fusion.
- Cases not described in the indications.
- Patients unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or acquired bone friability or calcification problem.
- Pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Cases where implant components selected for use would be too large or too small to achieve successful results.
- Cases requiring mixing metals from two different components or systems.
- Patients in which implant use would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

Nota bene: although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- Severe bone resorption.
- Osteomalacia.
- Severe osteoporosis.

WARNINGS and POTENTIAL RISKS

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 results. When additional support instrumentation is used, refer to the package insert for requirements and limitations related to those devices. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in successful use of the system.

Further, proper selection and compliance of patients greatly affect results. Patients who smoke were shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous spinal surgery.

This device was designed for single patient use only. Do not reprocess or reuse this product. Reuse or reprocessing may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

PRECAUTIONS

Physician note: although the physician is the learned intermediary between the company and the patient, the important medical information in this document should be conveyed to the patient.

For MRI information to convey to the patient, reference the MRI INFORMATION section of this document

POSSIBLE ADVERSE EFFECTS

Adverse effects may occur when the device is used either with or without associated instrumentation. Risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include:

- Implant migration.
- Breakage of the device.
- Foreign body reaction to implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on surrounding tissues or organs.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Infection.
- Bone fracture or stress shielding at, above, or below the level of surgery.
- Non-union (or pseudoarthrosis).
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain.
- Neurovascular compromise including paralysis, temporary or permanent retrograde ejaculation in males, or other types of serious injury.
- Cerebral spinal fluid leakage.
- Hemorrhage of blood vessels and/or hematomas.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Autogenous bone graft donor site complication.
- Inability to resume activities of normal daily living.
- Early or late loosening of the device.
- Urinary retention, loss of bladder control, or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or autogenous bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Loss of or increase in spinal mobility or function.
- Reproductive system compromise including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems (e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Change in mental status.
- Cessation of any potential growth of the operated portion of the spine.
- Death.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

MR Conditional

MRI Safety Information

A person with the Anteralign™ LS Spinal System and optional Anteralign™ LS coverplate may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device name	Anteralign™ LS Spinal System and optional Anteralign™ LS coverplate
Static Magnetic Field Strength (B0)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
RF Receive Coil Type	Any
Operating mode	Normal operating mode
Maximum Whole-Body SAR	2 W/kg (normal operating mode)
Maximum Head SAR	3.2 W/kg (normal operating mode)
Scan duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact that extends approximately 36mm from the device.

DIRECTIONS FOR USE

Installation and positional adjustment of the coverplate must only be done with the special ancillary instruments and equipment supplied with the coverplate.

INTRAOPERATIVE

- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implants may cause injury to patients or operative personnel.

INSTRUCTIONS FOR USE

1. Once the Anteralign ™ LS Interbody fusion device and integrated fixation screws have been placed insert coverplate by placing it over the Anteralign™ LS interbody and screws. Fix the coverplate to the interbody. Turn the locking mechanism such the locking screw is covered, continue to turn until a positive stop is felt.
2. Visually confirm coverplate placement is flush with the front of the interbody

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

- Detailed instructions on use and limitations of the device should be given to the patient.
- Patients must be warned that loosening, and/or breakage of the device are complications which may occur as a result of excessive weight bearing, muscular activity or sudden jolts or shock to the spine.
- To allow maximum chances for a successful surgical result, patients or devices should not be exposed to mechanical vibrations that may loosen the device construct. Patients should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. Patients should be advised not to smoke or consume excess alcohol during the bone fusion process.
- Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if components loosen, migrate, and/ or break, devices should be revised and/or removed immediately before serious injury occurs.
- The implants are interbody devices and are intended to stabilize the operative area during the fusion process. Retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

CARE AND HANDLING

The sterile packaged kit containing the coverplate and coverplate insertion instruments should be intact upon receipt. Once the seal on the sterile package is broken, the product should not be re-sterilized. Damaged packages or products should not be used and should be returned to the manufacturer (see Tyber Medical contact details below.

Limitations on Reprocessing

Devices are provided sterile and should only be used if they are marked sterile and clearly labeled as such in an unopened sterile package provided by the company. Only sterile products should be placed in the operative field. Implants should never be reprocessed or reused.

Storage

Store sterile packed kits in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

RETRIEVAL AND ANALYSIS OF REMOVED IMPLANTS

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant during handling and shipping. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent the spread of bloodborne pathogens. If a device is defective or damaged, request a replacement. Refer to section REPORTING OF SERIOUS ADVERSE EVENTS OR INCIDENTS for product problems.

DISPOSAL

Observe internal hospital/institution procedures, practice guidelines, and/or government regulations for proper handling and disposal of the Anteralign™ LS coverplate System.

REPORTING OF SERIOUS ADVERSE EVENTS OR INCIDENTS:

Report all Serious Event or Incidents to the manufacturer (see the manufacturer contact details below) and to your local Regulatory Authority

If a device is defective or damaged, please include, at a minimum, the following in your correspondence with the manufacturer:

- Device Part Number
- Device Lot Number
- Description of defect or damage
- Information on whether the device is available for return

LBL-ME202508 Rev. A-01 (2026-07-15)

Tyber Medical, LLC
83 South Commerce Way, Suite 310
Bethlehem, PA 18017
Phone: +1 (866) 761-0933
Fax: +1 (866) 889-9914

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
Phone: +1 800 933 2635 (USA)

SYMBOL GLOSSARY

SYMBOL	MEANING
	Caution: Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician.
	Reference Number
	Lot Number
	Country of Manufacture / Date of Manufacture
	Expiration Date
	Sterilized Using Irradiation
	Do Not Re-Use
	Do Not Use If Package Is Damaged
	Do Not Re-Sterilize
	Consult Instructions for Use
	Distributor
	Manufacturer
	Unique Device Identifier
	MR Conditional
	Medical Device
	Double Sterile Barrier