Manufactured by:
Southern Medical (Pty) Ltd
Building 10,
Southern Implants Office Park,
1 Albert Road,
Irene, 0062
South Africa
Tel: +27 12 667 6243/4
Email: info@southmed.co.za

European Representative:
Medical Device Safety Service
GmbH Schiffgraben
41 Hannover 30175 Germany

IMPORTANT: PLEASE READ

For detailed information on the Southern Standalone Lateral Screw Fixated Cage (Unity+), please consult the Unity+ Surgeons' Manual or IFU at southmed.co.za

Description:
The Standalone Lateral Lumbar Cage (Unity+, also known as the LLC-SA) is manufactured from biocompatible poly-ether-ether-ketone (PEEK) (ASTM F2026) with tantalum (ASTM F560) markers, a titanium (ASTM F136) lateral screw plate and titanium (ASTM F136) fixation locking screws. Surgical instrumentation is manufactured from surgical grade stainless steel (ASTM F899).
Variants: All Unity+ cages are available in an additional configuration whereby the vertebral contacting surfaces are titanium (ASTM F1580) plasma coated.

Radioactivity warning:
No radioactive substance or radioactivity.

Intended purpose:
The intervertebral endoprostheses are intended as treatment options for pain and functional disorders specific to the lumbar vertebral column. The aim of the device is to provide support between two vertebral bodies and initial immobilization of these bodies whilst simultaneously providing space for bone graft so that a fusion of the two vertebral bodies will in time be attained. Preferred patients are those that have instability due to degenerated discs and/or facet joints causing pain, loss of disc height, spondylolisthesis or change in the normal curvature of the spine.

Intended performance and undesirable side-effects:
The Unity+ is intended for fixation of the lumbar spine, excluding L5-S1. Revision surgery for device retrieval or additional instrumentation must be possible in the event of failure to fuse or poor clinical outcome.

Indications:
- Axial low back pain without severe central canal stenosis
- Single level degenerative disc disease and instability with radiographic evidence (e.g. MRI)
- Degenerative spondylolisthesis (Grade II)
- Discitis, vertebral osteomyelitis (without active infection)
- Failed conservative treatment (at least 6 months)
- Intractable low-back pain without stenosis or spondylolisthesis
- Isthmic spondylolisthesis
- ODI>30
- Patients between 18 and 80 years
- Primary surgery for certain advanced disc diseases
- Pseudoarthrosis or failed arthrodesis
- Revision surgery for post-discectomy syndrome
- Recurrent disc herniation and radiculopathy
- Stenosis and associated spondylolisthesis
- TDR revision
- Treatment of instability with DDD (or post laminectomy instability)
- VAS>40

Contraindications:
- Adjacent levels instrumented with pedicle screws
- Arachnoiditis
- BMI>40
- Bone metabolic diseases
- Diabetes mellitus
- Fractures of the vertebrae envisioned for instrumentation
- Incompetent/missing posterior arch at the affected level
- Infectious disease.
- Known metal allergy (titanium)
- Treatment at L5-S1 level
- Lumbar hyperlordosis>70° between the end plate of the lumbar vertebral body and the end plate of the sacral vertebral body
- Major mental illnesses and psychosocial disorders (Waddell>3/5)
- Major spinal instability
- Malignant diseases with or without bone metastases
- Osteomalacia
- Osteoporosis or osteopenia
- Paget's disease
- Patients with Grade II or Grade III spondylolisthesis requiring decompression
- Pregnancy
- Primary spinal deformity
- Requires laminectomy at level surgery
- Rheumatoid arthritis
- Spinal fractures
- Spinal tumours
- Spondylosis
- Spondylolisthesis greater than Grade 3
- Systemic or local infection
- Undergoing chemotherapy or radiation treatment or chronic use of steroids

Surgical Risks:
- Abdominal hernia
- Allergic or other reaction to anesthesia
- Blood loss or hemorrhage
- Death
- Ileus
- Infection
- Pain
- Peritonitis
- Pneumonia
- Pneumothorax
- Pulmonary embolism
- Thrombosis
- Surgical instrument failure

Risks Associated with Abdominal Spinal Systems:
- Acute heart failure
- Adjacent segment disease
- Annular ossification
- Dural injury
- Facet joint deterioration
- Hematoma or seroma
- Heterotopic ossification
- Implant breakage
- Implant collapse or subsidence into adjacent vertebrae
- Implant degradation
- Implant displacement/migration
- Impotence
- Incontinence
- Kidney or ureter injury
- Metal ion release
- Nerve root injury
- Neurologic deterioration; clumsiness, foot drop, limp, short step
- Slow moving gait
- Vessel damage
- Wear debris generation
- Numbness
- Osteophyte resorption
- Perineural fibrosis
- Removal of the device in the post-op or follow-up period
- Reoperation/revision at the treatment level with or without removal or modification of any or all components
- Retrograde ejaculation
- RSD (reflex sympathetic dystrophy)
- Soft tissue penetration by screw
- Spinal cord injury due to instruments being forced too deep
- Spinal instability
- Spinal stenosis (narrowing of the spinal canal)
- Spondylolisthesis acquisita
- Spondylosis acquisita
- Spontaneous fusion
- Sterility
- Supplemental fixation
- Tumor formation/ carcinogenesis potential
- Vertebral fracture

Direct Lateral Approach Surgical Risks:
- Allergic or other reaction to anesthesia
- Atrial fibrillation
- Blood loss or hemorrhage
- Dysesthesias: Genito/Femoral
- Gastric volvulus
- Illeus (and transient ileus)
- Infection
- Iliac vein laceration
- Iliac artery thrombosis
- Incisional hernia
- Meralgia paresthetica
- Motor injury
- Myocardial fibrillation
- Osteolysis or vertebral inflammation
- Pain
- Peritoneal catheter occlusion
- Psoas spasm
- Permanent femoral injury
- Peritoneal or abdominal adhesions
- Peritonitis
- Pneumonia
- Pneumothorax
- Pulmonary embolism
- Re-intubation
- Transfusion Thrombosis (Iliac artery thrombosis and ileo-femoral venous thrombosis)

Recommended Surgical Procedure:
Refer to the surgical procedure provided by Southern Medical (Pty) Ltd.

USAGE WARNING:
Improper technique in implant placement can result in implant failure. The Unity+ devices are not intended as the sole means of spinal support. In absence of bone graft or fusion the implant or implant components can be expected to pull out, bend or fracture as a result of everyday mechanical stresses. Placement of devices is limited to surgeons. Refer to the surgical procedure and product brochure for more information.

Sterility:
All implants are supplied sterile, and are for single use only before the labeled expiration date. Do not re-use implants. Do not use implants if the packaging has been damaged or previously opened, or if the expiration date has passed. If uncertain be sure to contact a Southern Medical Representative.

RE-STERILIZATION AND RE-USE WARNING:
Do not re-sterilize implants produced sterile. Implants are sterilized by gamma irradiation. Re-sterilization could cause material degradation and could result in surgical rejection and/or post-operative infection. The implant is designed for single patient use only and must never be reused. An explanted implant must never be re-implanted. Reuse or re-implantation may result in cross-contamination or infection.

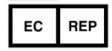
Magnetic Resonance Imaging (MRI)
The Unity+ devices have not been tested for adverse effects under MRI. The Unity+ is manufactured from non-ferromagnetic materials. Non-clinical evaluations have demonstrated that Unity+ devices are MR Conditional based on a Cobalt Chrome worst case device. Patients can be scanned safely immediately after implantation under the following conditions:
- Static magnetic field of 3.0-Tesla (3.0T) or less
- Maximum spatial gradient field less than or equal to 10T/m.
- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of:
  - 2 W/kg for 15 minutes of scanning at 1.5T.
  - 2 W/kg for 15 minutes of scanning at 3.0T.

MR image quality may be compromised if the area of interest is the same or relatively close to the position of the device, and it may be necessary to optimize the MR imaging parameters.

Risks of placing implants in or near a magnetic field include: (1) movement of ferromagnetic components, (2) localised heating of components caused by radio frequency induction heating and (3) image artifacts created by interaction between metallic components and the magnetic field.

Post Implantation:
The surgeon/physician's postoperative directions, indications and warnings to the patient with subsequent patient compliance are vital to successful fusion. The subject must refrain from physical activity for several months. Physical movement must be minimized. Subjects will be instructed not to engage in activities requiring lifting, bending, twisting or excessive movement for several months post-operatively. The subject must not be exposed to electrical shock and mechanical vibrations. Directly after the operation, subjects will be placed in a brace until fusion occurs. After a couple of months, the subject may return to the workplace if the work environment does not entail excessive physical activities. Car journey duration must be minimized, preferably avoided.

Descriptions of Symbols Used in Packaging:

USE BY	
LOT NUMBER	
MANUFACTURER ADDRESS	
DATE OF MANUFACTURE	
DO NOT REUSE	
STERILIZED USING IRRADIATION	
CAUTION	
AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	
CONSULT THE INSTRUCTIONS FOR USE	
DO NOT RESTERILIZE	
DO NOT USE IF PACKAGING IS DAMAGED