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## IMPORTANT: PLEASE READ

**For detailed information on the LLC devices, please consult the applicable Surgical Manual.**

### DESCRIPTION:

The Southern Lateral Lumbar Cage (LLC) family includes the Unity, Unity+, and Unity Genesis devices. The devices are straight and narrow, wedge-shaped interbody fusion cages that are intended to be used in Extreme Lateral Interbody Fusion (XLIF) or Direct Lateral Interbody Fusion (DLIF) procedures.

**Unity:**
The device consists of a Polyetheretherketone (ASTM F2026) cage with Unalloyed Titanium (ASTM F67) radiographic markers that is intended to be implanted with two Ti-6Al-4V ELI Titanium Alloy (ASTM F136) screws.

**Unity+:**
The device consists of a Polyetheretherketone (ASTM F2026) cage with Tantalum (ASTM F67) radiographic markers that is intended to be implanted with a Ti-6Al-4V ELI Titanium Alloy Screw Plate and Cap, as well as four Ti-6Al-4V ELI Titanium Alloy (ASTM F136) screws.

**Unity Genesis:**
The device consists of a 3D printed Ti-6Al-4V ELI (ASTM F3001) cage that is intended to be implanted with a Ti-6Al-4V ELI Titanium Alloy Screw Plate and Cap, as well as four Ti-6Al-4V ELI Titanium Alloy (ASTM F136) screws.

All three device variants have bone pockets that are intended to be filled with autograft or allogenic bone graft.

### INDICATIONS FOR USE:

The devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one 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. Patients may also have up to Grade I spondylolisthesis at the involved level(s). The devices may also be used in patients with pseudarthrosis / non-union from previous unsuccessful fusion surgery. Patients should have undergone at least six weeks of non-operative treatment. The devices are to be packed with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The Unity cage is intended to be implanted with two screws. The Unity+ and Unity Genesis cages are intended to be implanted with a screw plate, screw plate cap and four screws. The specified components should be used to ensure adequate fixation of the implant.

### CONTRA-INDICATIONS:

Contra-indications include, but are not limited to:

- Allergy or hypersensitivity to any of the implant materials
- Active systemic or localised infection and/or inflammation
- Spondylolisthesis greater than Grade I
- Bone diseases, such as severe osteoporosis, osteopenia, osteomalacia or Paget's disease, that compromise bone quality and may interfere with device placement, healing and/or fusion
- Pregnancy
- Patient anatomy or pathology that prevents full insertion and correct usage of the device
- Use with components from other manufacturers.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient that has inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Reuse or multiple use.
- Any other conditions that may place excessive stress on the device and/or bone, such as morbid obesity, tumours, fractures, strong rotational deformation or inadequate tissue coverage. The decision to use a device in patients with such conditions must be made by a healthcare professional after taking into consideration the benefits and risks to the patient.
- The use of this device is relatively contra-indicated in patients whose activity, occupation, mental capacity, history of substance abuse or other lifestyle factors may prohibit their ability to comply with post-operative care instructions. These patients may place undue stress on the device and may be at higher risk of implant failure.

### ADVERSE EFFECTS AND RISKS OF USE:

- Device failure / fracture
- Loss of fixation (e.g., cage loosening or migration)
- Pseudarthrosis or delayed fusion
- Fracture of the vertebrae
- Adjacent segment disease / degeneration
- Infection and/or inflammation
- Allergic response to foreign body
- Neural or Neurological injury
- Vascular injury
- Thrombosis / thromboembolic event
- Visceral injury
- Loss of spinal mobility and/or function at the treated level(s)
- Chronic pain
- Spinal Encroachment
- General surgical complications (including postoperative ileus, incisional hernia and cyst formation)
- Reoperation or revision surgery
- Death

### USAGE WARNING:

The device should only be implanted by qualified surgeons with knowledge of the correct and safe use of the device and its associated instrumentation. Refer to the surgical manual provided by Southern Medical (Pty) Ltd. If uncertain, contact a Southern Medical Representative.

Autograft or allogenic bone graft should be use din combination with the device. Failure to use bone graft may result in non-union.

The Unity cage is intended to be implanted with two screws. The Unity+ and Unity Genesis cages are intended to be implanted with a screw plate, screw plate cap and four screws. Failure to use the components as specified may lead to mechanical failure of the device, non-union and/or cage migration/expulsion.

Correct handling of the device(s) is extremely important. The desired clinical outcome may not be achieved if the usage instructions are not followed.

### STERILITY:

Implants are sterilised by gamma irradiation and are supplied **STERILE**. **DO NOT RE-STERILISE** devices supplied sterile. Re-sterilisation can cause material degradation and could result in surgical rejection and/or post-operative infection.

Do not use implants if the packaging has been damaged or previously opened, or if the expiration date on the label has been exceeded.

### RE-USE WARNING:

The implants are intended for **SINGLE USE** only and **MAY NOT BE RE-USED**. An explanted device must never be re-implanted. Re-use or re-implantation may result in cross-contamination or infection.

### INSTRUMENTATION:

Only the surgical instruments provided by the manufacturer should be used. Instruments are provided non-sterile and must be cleaned and sterilised before use in accordance with the validated methods prescribed in IFU-100.

### STORAGE:

No special storage instructions. Storage conditions must not prematurely deteriorate device packaging or degrade/contaminate the packaging or the contents thereof in any way. Handle with care.

### RADIOACTIVITY INFORMATION:

No radioactive substance or radioactivity.

### MAGNETIC RESONANCE IMAGING (MRI):

The LLC devices have not been evaluated for safety in the MR environment. The devices have not been tested for heating or unwanted movement in the MR environment. The safety of the LLC devices in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

### POST-OPERATIVE CARE INSTRUCTIONS:

The surgeon, physician or other healthcare professional must provide appropriate post-operative care instructions to the patient and must ensure that the patient understands the potential consequences of non-compliance. To achieve the desired clinical outcome, the patient should be instructed to minimise physical activity as far as possible and avoid activities that require lifting, bending, twisting or excessive movement. Normal physical activities may only be resumed upon approval from a healthcare professional. It is recommended to schedule patient follow up consultations as necessary.

### DEVICE REMOVAL:

The devices are intended to remain in place for the duration of the patient's life. Surgical removal of the device is possible. Refer to the surgical manual for removal instructions. Any decision to remove the device must be made by a healthcare professional after taking into consideration the patient's general medical condition and the potential risk of a subsequent surgical procedure.

### DEVICE DISPOSAL:

Single-use devices that have been in contact with blood or bodily fluids/tissues must be decontaminated and discarded following the standard hazardous and/or biological waste disposal procedures of the healthcare facility. Users must wear gloves and take care to avoid sharp edges

### REPORTING:

Any device-related adverse events or incidents must be reported to the manufacturer as soon as possible.

### Descriptions of Symbols Used in Packaging:

| | | | |
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| USE BY | | CAUTION | |
| LOT NUMBER | LOT | CONSULT THE INSTRUCTIONS FOR USE | |
| MANUFACTURER | | DO NOT RESTERILISE | |
| DATE OF MANUFACTURE | | DO NOT USE IF PACKAGING IS DAMAGED | |
| DO NOT REUSE | | STERILISED USING IRRADIATION | STERILE R |
| CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN | Rx ONLY | | |