LITe® BIO Delivery System

Surgical technique
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Introduction

Placement of bone graft
The LITe BIO Delivery System may be used to deliver bone graft material lateral, ventral and/or dorsal to the implant. The LITe BIO Delivery System provides surgeons with a single handed, mallet free method to deliver allograft, autograft or synthetic bone graft material without obstructing direct visualization of the surgical site.
The LITe BIO Delivery System contains the following components:

### Sterile

- **Delivery Cannula**: Included in LITe BIO Delivery Sterile Package
- **Loading Syringe**: Included in LITe BIO Delivery Sterile Package
- **Plunger Seals**: Included in LITe BIO Delivery Sterile Package

*Figure 1: LITe BIO Delivery Sterile Package with Cannula (48288214)*

### Reusable

- **Loading Funnel**: 48288211
- **Loading Tool**: 48288212
- **Delivery Handle**: 48288213
- **Delivery Plunger**: 48288215

*Figure 2: Sterilization Tray and Lid (48288210)*
LITe BIO Delivery System

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Plunger/plunger seal assembly
Remove the Plunger Seal package from the sterile tray. Secure the seal by pressing the distal end of the Delivery Plunger within the wells of the package (Fig. 3).

Figure 3

Note: For ease of insertion either hold the tray in hand or place the tray on the back table.

Note: Ensure the seal is secure and fully seated on the distal end of the plunger (Fig. 4 and Fig. 5).

Figure 4  Figure 5

Plunger/cannula assembly
Place the Delivery Plunger with the Plunger Seal into the empty Delivery Cannula and advance to 5cc line (Fig. 6).

Figure 6
**Filling cannula with bone graft material**

To use the Loading Funnel, fill the **Loading Syringe** by hand with less than 5cc of bone graft material of choice.

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**Distal end of the Loading Funnel**

Place the cannula/plunger assembly into the distal end of the Loading Funnel (Fig. 7) and lock into place by aligning the tabs (Fig. 8).

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**Figure 7**

**Figure 8**

**Figure 9**

Secure Loading Syringe into the Loading Funnel by screwing into place. Tighten to secure (Fig. 9). Care should be taken not to over tighten.

Slowly depress the Loading Syringe plunger to advance the graft material. Continue to advance the graft material until the graft material partially fills the allotted space within the top of the Loading Funnel (Fig. 10).

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**Figure 10**

**Figure 11**

Use the Loading Tool to push small amounts of the bone graft material into the cannula. Repeat until all of the bone graft material is placed inside the cannula (Fig. 11). Remove the now filled cannula from the Loading Funnel.
Surgical technique

Holding the handle sideways with both hands, align the filled cannula with the slots of the Delivery Handle such that the tab of the cannula is aligned with the opening of the Delivery Handle. Push with two thumbs to secure (Fig. 12).

**Note:** It is very important that (1) the tabs of the cannula are fully engaged in the opening of the Delivery Handle and (2) the plunger is fully engaged within the retaining feature of the Delivery Handle at the most distal end. If either one is not fully engaged, the plunger will not advance as intended (Fig. 13 and Fig. 14).

**Placement**
Bone graft material may be placed in the interbody space prior to insertion of the implant. Please refer to the labeling of the specific bone graft material being used. The bone graft material being delivered must be used in accordance with the cleared or approved indications for use. The disc space must be distracted to at least 8.5mm, using either a paddle distractor or other self-retaining distraction device. If the disc space spans less than 8.5mm, the cannula MUST NOT be impacted or tamped into the disc space. This system is not intended to be a distraction device and is intended only for the delivery of graft material.
**Delivery**
The bone graft material can be inserted two ways; either by squeezing the trigger on the handle to advance the plunger, or by manually applying pressure to the back of the plunger so as to advance the plunger by hand. If advancing the plunger by hand, align the plunger with the back of the handle (Fig. 15) and squeeze the trigger to advance the remaining material.

![Figure 15](image)

**Removal**
To remove the cannula from the Delivery Handle, place the assembly on a hard surface such that the cannula connection opening of the Delivery Handle is facing up and press firmly on the body of the Delivery Handle.

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**Note:** Always use the Delivery Handle when delivering graft material.

**Note:** If the system will not function as intended during extrusion, do not apply significant force to the device in situ, rather remove it and check the bone graft material.

**Note:** It is the surgeon’s responsibility to ensure annular integrity and that bone graft is appropriately placed within the disc space. This can be confirmed with: 1) direct visualization and tactile feedback and, 2) intra-operative imaging using radio-opaque strips on cannula as guide.

**Note:** Ensure that not too much bone graft is delivered to the disc space as this may cause damage to surrounding anatomy.

**Note:** Ensure that the cannula does not advance into the disc space if you choose to manually advance the plunger.
# LITe BIO Delivery System

## Surgical technique

### LITe BIO Delivery System instruments

#### Sterile package

<table>
<thead>
<tr>
<th>Reference number</th>
<th>Description</th>
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<tbody>
<tr>
<td>48288214</td>
<td>LITe BIO Delivery Sterile Package with Cannula</td>
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  - Delivery Cannula*
  - Loading Syringe*
  - Plunger Seals*

* Included in LITe BIO Delivery Sterile Package

#### Reusable

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</tbody>
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**DESCRIPTION**
Stryker Spine’s LITe BIO Delivery System is a manually operated handheld device used to facilitate delivery of bone graft material to all orthopedic surgical sites. The system consists of a delivery cannula, a delivery plunger, a delivery plunger seal, a loading syringe, and a delivery handle. The delivery cannula is capable of holding and delivering up to 5cc of bone graft material.

**INDICATIONS**
Stryker Spine’s LITe BIO Delivery System is intended to deliver autograft, allograft, or synthetic bone graft materials to all orthopaedic surgical sites.

**CONTRAINDICATIONS**
Stryker Spine’s LITe BIO Delivery System is not designed or sold for any use except as indicated. The physician should be familiar with the contraindications of the bone graft material being delivered. The physician’s judgment is required to consider the patient’s risk factors prior to delivery of the graft material.

For a full list of contraindications, please refer to the labeling of the specific bone graft material being used.

**WARNINGS**
The components of the system should not be used with components of any other system or manufacturer. Any such use will negate the responsibility of Stryker Spine for the performance of the resulting system.

**GENERAL CONDITIONS OF USE**
Stryker Spine’s devices and instruments must be used in the manner described in the Surgical Technique brochures provided by Stryker Spine. Prior to using the devices and instruments, the surgeon shall have given careful consideration to all aspects of the surgical intervention as well as to the limits of the devices and instrumentation. Recommendations for use are provided in the Surgical Technique Brochure available from Stryker Spine representatives.

**POTENTIAL ADVERSE EFFECTS**
For a full list of potential adverse effects, please refer to the labeling of the specific bone graft material being used.

Additionally, incorrect maintenance, cleaning or handling may render the instruments unsuitable for their intended use, cause corrosion, dismantling, distortion and/or breakage or cause injury to the patient or operating staff.

Below is a list, albeit not exhaustive, of potential complications:
- Neurological lesion, paralysis, pain, lesion of the soft tissues, the visceral organs or the joints, in the event of incorrect use or breakage of the instruments.
- Infection, if the instruments are not properly handled.
- Dural leaks, compression of vessels, damage to nerves or nearby organs as a result of slippage or poor positioning of a faulty instrument.
- Damage caused by the involuntary releasing of the springs of certain instruments.
- Damage caused by the instruments used to bend or cut in-situ due to excessive forces occurring when they are used.
- Cutting the gloves or the skin of surgical staff.
- Tissue lesions on the patient or surgical staff and/or an increase in operating time as a result of having to disassemble the instruments during surgery.
- Crack, fracture or involuntary perforation of the bone.

As a result of the mechanical features required, most of the instruments are made of non-implantable materials. In the event an instrument breaks, no fragment must remain in the patient as this could cause post-operative complications such as allergies, infections, or complications of a biological nature associated with the release of metal components, possibly requiring further intervention.

**INFECTION**
Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

**INSTRUMENTS**
Specialized instruments are provided by Stryker Spine and must be used to assure proper performance of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative precaution, number of procedures, disposal attention. Instruments must be examined for wear or damage prior to surgery. Surgeons must verify that the instruments are in good condition and operating order prior to use during surgery.

Incorrect maintenance, cleaning, or handling may render the instruments unsuitable for their intended use, cause corrosion, dismantling, distortion and/or breakage or cause injury to the patient or operating staff.

**EXAMINATION PRIOR TO USE**
- The devices are provided sterile and non-sterile. The packaging of the sterile product must be intact at the time of receipt and use.
- The instruments must be used within the recommended sterile shelf-life as indicated on the packaging.
- Instruments should be examined for wear or damage by physicians and staff in operating centers prior to surgery.
- The examination shall include a visual and functional inspection of the working surfaces and articulation points, and springs. It should also include verifying all welded connections, that all components are present, and the cleanliness of the orifices and cavities, as well as the absence of any cracks, distortion, impact, corrosion or other changes.
- Certain surgical intervention requires the use of instruments which include a measuring function. These are to be inspected for wear and the clear visibility of any surface markings.
- Stryker Spine and its representative are available to help carry out proper instrument inspections.
- Stryker Spine shall not be responsible in the event of the use of instruments that are damaged, incomplete, show signs of excessive wear and tear, or that have been repaired outside the control of Stryker Spine.
- Any faulty instruments must be replaced prior to any intervention.
PRE-OPERATIVE PRECAUTIONS
Stryker Spine’s devices can only be used by physicians who are fully familiar with the surgical technique required and who have been trained to this end. The physician operating must comply with any operating procedure described in the surgical technique provided by Stryker Spine. Extreme care must be taken when the instruments are used near vital organs, nerves, or vessels.

COMPLAINTS
Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and/or its performance, should notify Stryker Spine or its representative. Moreover, if a device has malfunctioned, or is suspected of having malfunctioned, Stryker Spine or its representative must be advised immediately.

If a Stryker Spine’s product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or Stryker Spine must be informed as soon as possible by telephone, fax or in writing.

For all complaints, please give the name and reference along with the batch number of the component(s), your name and address and an exhaustive description of the event to help Stryker Spine understand the causes of the complaint.

For further information or complaints, please contact:
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2 Pearl Court, Allendale, NJ
07401-1677 - USA
Tel: +1 201 749 8000
A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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