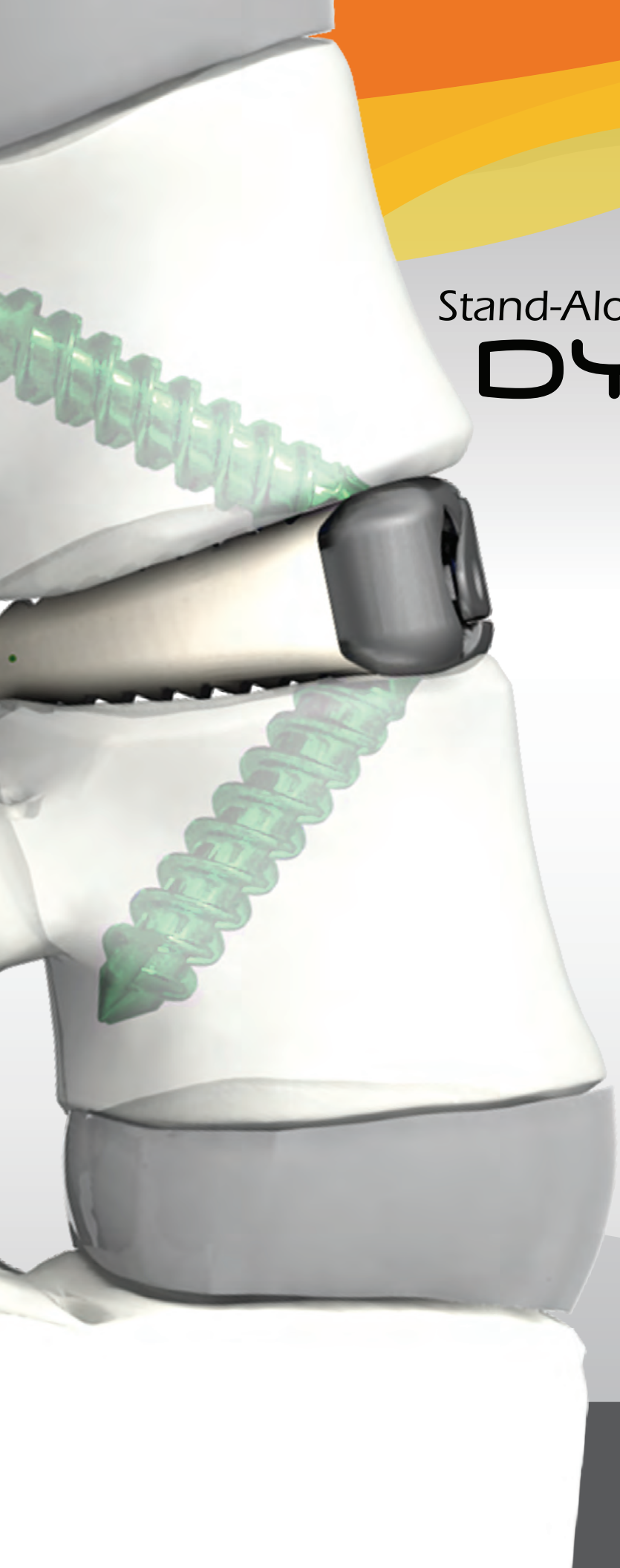


Stand-Alone Anterior Lumbar System®

DYNA-LINK

SURGICAL TECHNIQUE GUIDE

Life Spine®
Designs For Life.®

Stand-Alone Anterior Lumbar System

DYNA-LINK®

CONTENTS

Stand-Alone Anterior Lumbar System

DYNA-LINK®

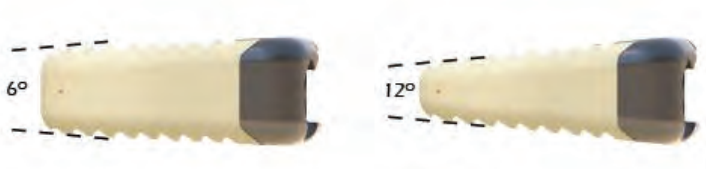
Introduction

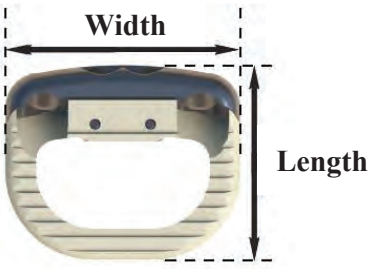
The DYNA-LINK Stand-Alone Anterior Lumbar System is a zero-profile, stand-alone device that offers surgeons a safe and reliable alternative to 360° fusion procedures. In addition to providing immediate fixation without the need for intraoperative patient repositioning, multiple footprints and heights are available to accommodate various patient anatomies and pathologies to promote fusion.

Features and Benefits

Features	Benefits
Zero Anterior Column Profile	Eliminates potentially hazardous vertebral column profile which can disrupt great vessels
Large, Open Graft Windows	Maximize visibility and bone graft containment
Ample Screw Angulation	40° angulation contributes to increased screw thread/cortical bone contact for improved pull-out resistance
Multiple Instrumentation Offerings	Accommodates different surgeon preferences and anatomical differences

Implants





Interbody				
Part Number	**Width x Length**	**Anterior Height**	**Posterior Height**	**Lordosis**
80-3226-0611	32mm x 26mm	11mm	8.5mm	6°
80-3226-0613	32mm x 26mm	13mm	10.5mm	6°
80-3226-0615	32mm x 26mm	15mm	12.5mm	6°
80-3226-0617	32mm x 26mm	17mm	14.5mm	6°

Part Number	Width x Length	Anterior Height	Posterior Height	Lordosis
80-3226-1211	32mm x 26mm	11mm	6mm	12°
80-3226-1213	32mm x 26mm	13mm	8mm	12°
80-3226-1215	32mm x 26mm	15mm	10mm	12°
80-3226-1217	32mm x 26mm	17mm	12mm	12°

80-3830-0611	38mm x 30mm	11mm	8mm	6°
80-3830-0613	38mm x 30mm	13mm	10mm	6°
80-3830-0615	38mm x 30mm	15mm	12mm	6°
80-3830-0617	38mm x 30mm	17mm	14mm	6°

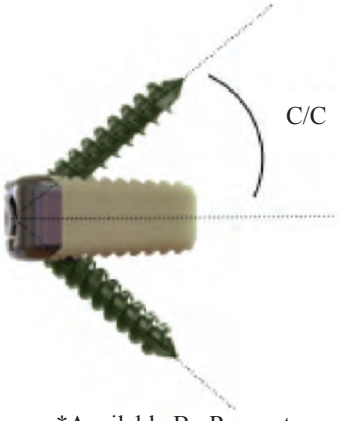
80-3830-1211	38mm x 30mm	11mm	5.25mm	12°
80-3830-1213	38mm x 30mm	13mm	7.25mm	12°
80-3830-1215	38mm x 30mm	15mm	9.25mm	12°
80-3830-1217	38mm x 30mm	17mm	11.25mm	12°

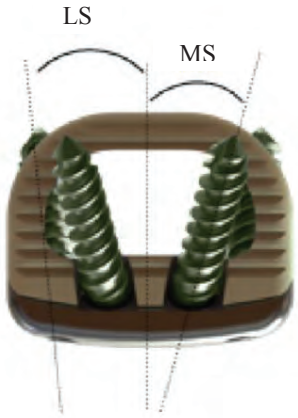
Fixed Screws		
Part Number	**Diameter**	**Length**
80-155-20	5.5mm	20mm
80-155-25	5.5mm	25mm
80-155-30	5.5mm	30mm

*Variable Screws		
Part Number	**Diameter**	**Length**
80-255-20	5.5mm	20mm
80-255-25	5.5mm	25mm
80-255-30	5.5mm	30mm

Screw Angulation	
Cephalad/Caudal (C/C)	40°
Medial Screws (MS)	15°
Lateral Screws (LS)	5°

Lock Plate	
Part Number	**Description**
80-620	Lock Plate





*Available By Request

Instruments

Instruments available for use with the DYNA-LINK Stand-Alone Anterior Lumbar System.

Modular Distractor and Distractor Tips

Rasp/Tamp

Trial Installer

Trial, 32mm x 26mm & 38mm x 30mm, 6°

Trial, 32mm x 26mm & 38mm x 30mm, 12°

Implant Installer

Lateral Drill Guide/Installer

Anterior Lumbar Graft Packing Block

Anterior Lumbar Graft Packing Tool

Graft Containment Shims, 11mm – 17mm

Awl

Fixed Angle Awl

Angulating Awl

Angulating Instrument Guide

Centering Bent Awl*

Drill

Fixed Angle Drill

Angulating Drill

3.5mm Hex Screwdriver

3.5mm Hex Angulating Screwdriver

*Available By Request

¼ Square Ratcheting Straight Handle

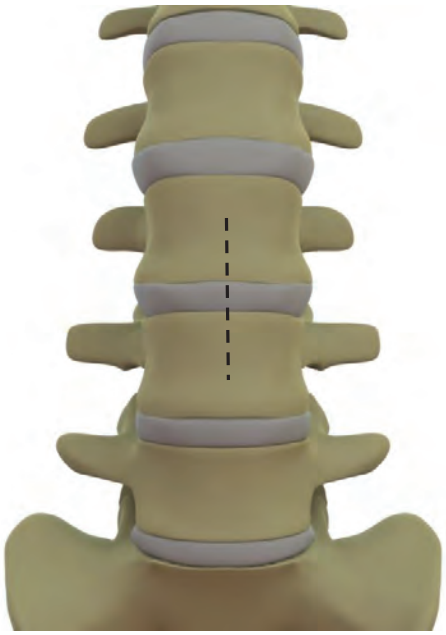
Lock Plate Installer

¼ Square Torque Handle, 15 in-lbs

Slap Hammer

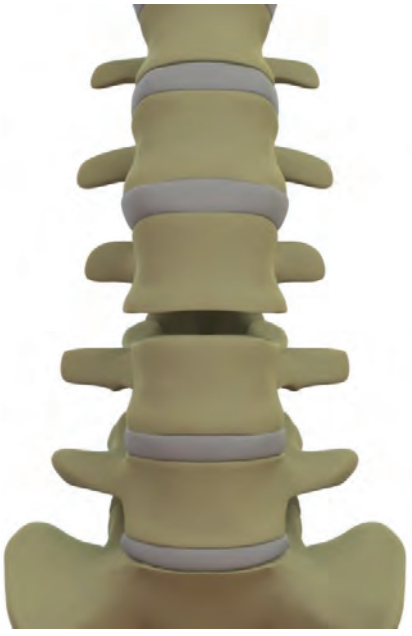
The surgical approach is dependent upon the level to be treated. However, direct anterior access is required for insertion of the implant.

1. **Preparation**
   Preoperative planning, knowledge of the surgical technique, and proper implant selection and placement are important considerations when using the DYNA-LINK Stand-Alone Anterior Lumbar System. Intraoperative views will help locate the proper operative disc level, thus ensuring the incision and exposure allow adequate visualization into the disc space.



2. **Exposure**
   The DYNA-LINK implant must be inserted from a direct anterior approach. The segment should be exposed to produce sufficient space on either side of the vertebral midline, equal to half the width of the interbody (32mm or 38mm spacer width).

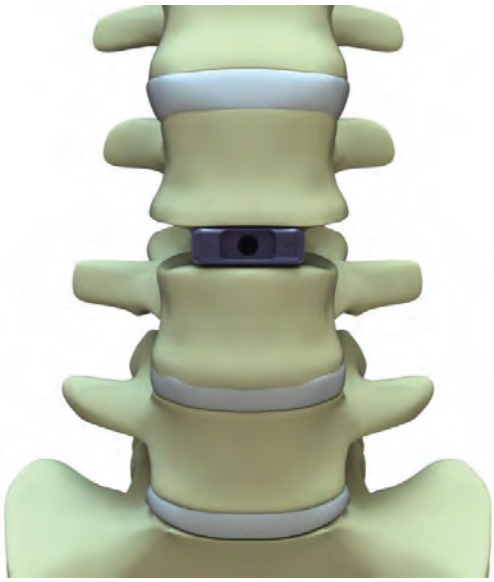
NOTE: When the interbody is inserted, visualization of the entire anterior plate is necessary for insertion of the bone screws and lock plate. Proper consideration should be given to the exposure to accommodate subsequent instruments and ultimately implant insertion.



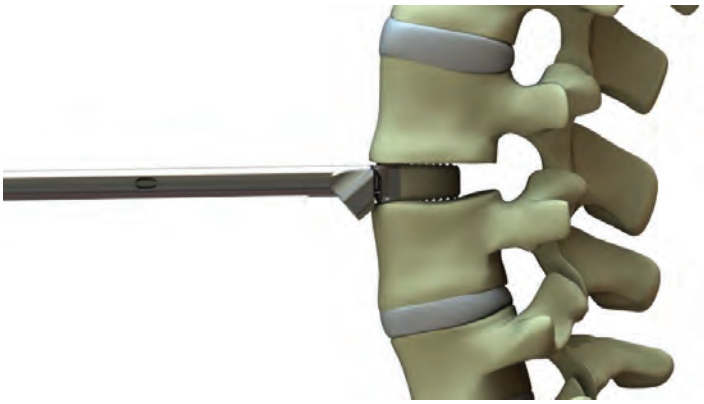
3. **Discectomy/Endplate Preparation**
   Using general surgical instruments, perform a thorough discectomy. Care should be taken to ensure the postero-lateral corners are freed of disc material.

   The Rasp in the set can be used to remove the cartilaginous layer of the endplates. This will aid in the creation of bleeding bone in order to promote spinal fusion. Appropriate endplate preparation will optimize surface contact with the selected DYNA-LINK interbody and bone graft material.

4. **Determine Implant Size**
   Select the appropriate sized Trial and attach to the Trial Installer. Insert the Trial into the target disc space. Light impaction may be needed to fully insert the Trial. Fluoroscopy may be used to confirm the fit and geometry of the selected Trial.



5. **Implant Insertion (Preferred Method)**
   The Lateral Drill Guide/Installer may be used to insert the interbody and allows for screw hole preparation of the lateral screw holes. Prior to screw hole preparation, ensure the lateral screw holes on the Guide are correctly lined up with the lateral screw holes on the implant. Screws may also be placed through the Lateral Drill Guide/Installer.



Insert the interbody while taking care to align it in the center of the disc space. Light impaction may be needed to fully insert the interbody. Fluoroscopy should be used to verify the desired position prior to screw hole preparation.

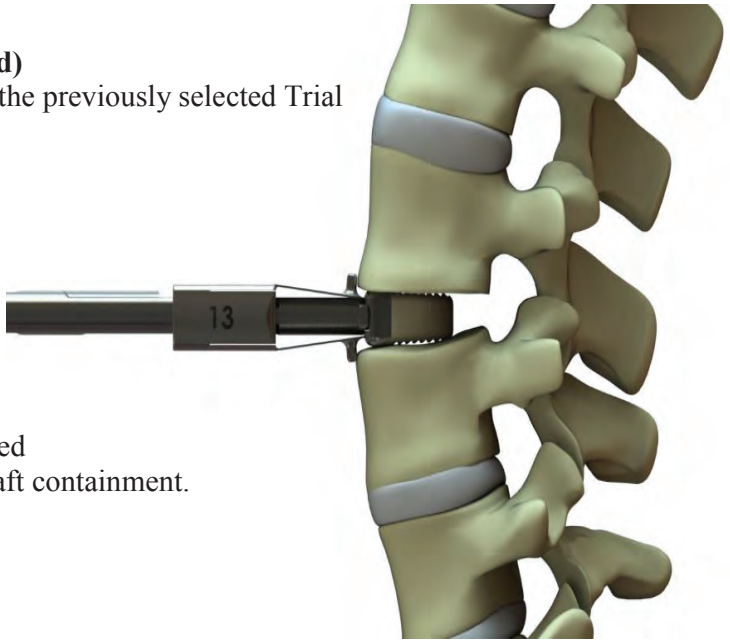
NOTE: The Lateral Drill Guide/Installer cannot be used with the Graft Containment Shims, although the Lateral Drill Guide/Installer can be attached to the interbody after Graft Containment Shims have been removed from the disc space.

Once complete with the lateral screw holes, remove the Lateral Drill Guide/Installer to complete the medial screw holes.

Implant Insertion (Alternative Method)
Select the interbody that corresponds to the previously selected Trial and attach to the Implant Installer.

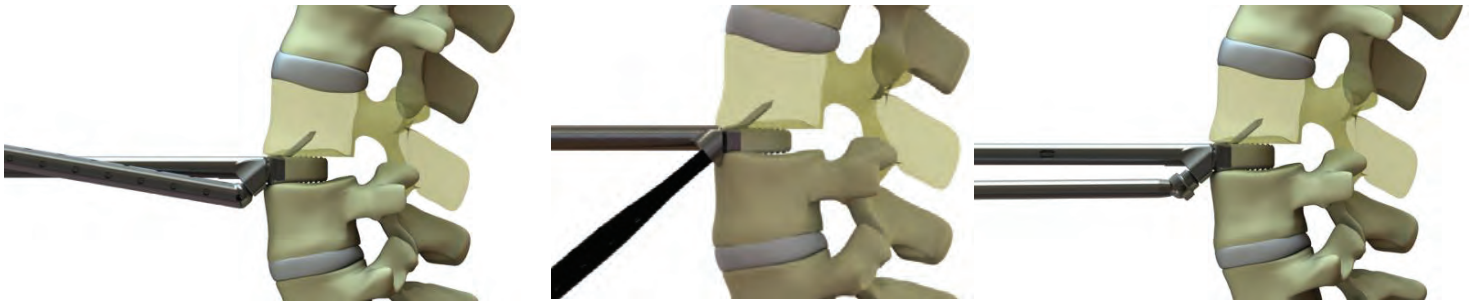
Insert the interbody while taking care to align it in the center of the disc space. Light impaction may be needed to fully insert the interbody. Fluoroscopy should be used to verify the desired position prior to screw hole preparation.

Graft Containment Shims may be attached to the Implant Installer to aid in bone graft containment.



6. Screw Hole Preparation

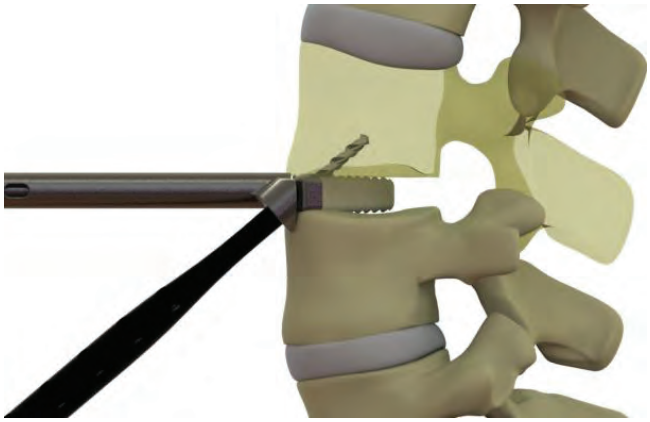
Awl
Insert the Awl, Fixed Angle Awl, or Angulating Awl through the Lateral Drill Guide/Installer. If using the Angulating Awl, the Angulating Instrument Guide may also be used to control the tip angle. The stop on the Awl prevents it from advancing more than the depth of a 20mm screw into the vertebral body.



IMPORTANT: Use caution that the Awl, Fixed Angle Awl, or Angulating Awl does not move the interbody during screw hole preparation.

Drill
If desired, the Drill, Fixed Angle Drill, or Angulating Drill may be used to further prepare the screw hole. If the Angulating Drill is used, the Angulating Instrument Guide may also be used to control the tip angle. The stop on the Drill prevents it from advancing more than the depth of a 20mm screw into the vertebral body.

IMPORTANT: Use caution that the Drill, Fixed Angle Drill, or Angulating Drill does not move the interbody during screw hole preparation. For particularly hard bone, drilling is recommended.



7. **Screw Insertion**
   Attach an appropriately sized screw to either the Screwdriver or Angulating Screwdriver and insert the screw. If using the Angulating Screwdriver, the Angulating Instrument Guide may also be used to control the tip angle. Utilize the same technique to place the remaining screws. Confirm the bone screw positions fluoroscopically.

The DYNA-LINK Stand-Alone Anterior Lumbar System is intended for use with four titanium alloy screws which are provided with the system. If the physician chooses to use fewer than four of the provided screws, supplemental spinal fixation that is cleared for use in the lumbosacral spine must be used.

NOTE: Knowledge of the overall construct length is a key determinate when selecting the appropriately sized screw length.

8. Lock Plate Insertion

Attach the Lock Plate Driver to the ¼ Square Torque Handle, 15 in-lbs.

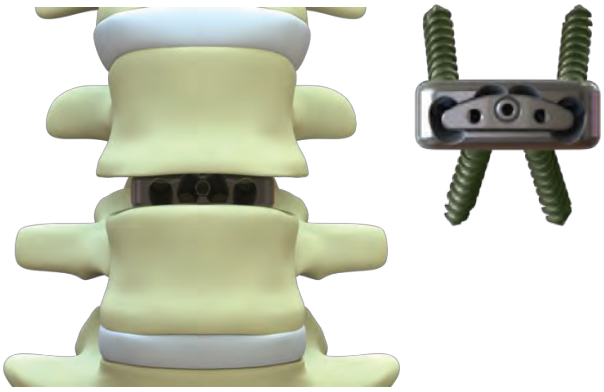
To engage the Lock Plate Driver to the lock plate, pull up on the sleeve of the Lock Plate Driver. Place the Lock Plate Driver into the lock plate screw with the outer pegs attaching to the guide holes of the lock plate.

To ensure that the Installer is fully engaged with the lock plate, push down on the sleeve.

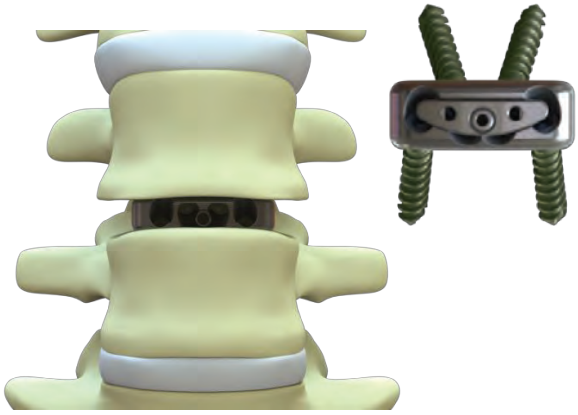
NOTE: When the curve of the lock plate is facing up, assure the laser marking "UP" is in line with the curve of the lock plate

NOTE: When the curve of the lock plate is facing down, assure the laser marking "UP" is **not** in line with the curve of the lock plate

Align the lock plate with the interbody and thread the screw in.

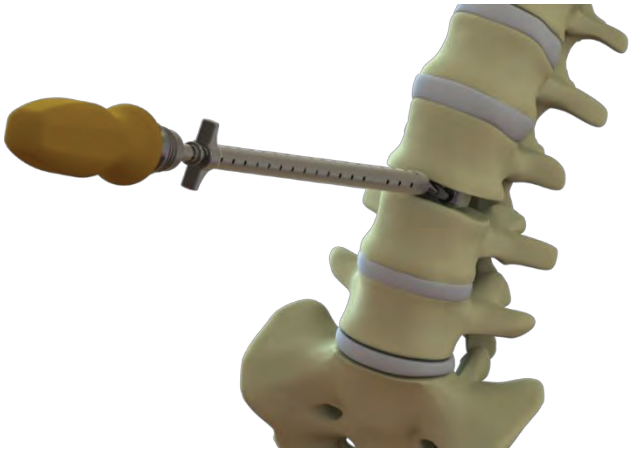


If this is the view of the interbody after placement, the curve of the lock plate is cephalad.



If this is the view of the interbody after placement, the curve of the lock plate is caudal.

Turn the ¼ Square Torque Limiting Handle, 15 in-lbs clockwise until an audible click is heard and tension is released in the handle.



9. Removal/Revision

All implants can be removed by performing the insertion steps in reverse. If necessary, utilize the Implant Installer to remove the Interbody following removal of the Lock Plate and explantation of the Bone Screws. If needed, the Slap Hammer can be attached to the Trial/Implant Installer to help with removal of the Interbody.

LIFE SPINE

Dyna-Link® Stand-Alone Anterior Lumbar System

Standard Product Insert

Life Spine
13951 S. Quality Drive
Huntley, IL 60142
USA

Tel: 847-884-6117
Fax: 847-884-6118
www.lifespine.com

Important Information on the DYNA-LINK Stand-Alone Anterior Lumbar System

Description:
The DYNA-LINK Stand-Alone Anterior Lumbar System implants are intervertebral body fusion devices comprised of a variety of spacer implants manufactured from Polyetheretherketone (PEEK-OPTIMA LT1) with tantalum markers. The spacers are hollow to permit packing with bone graft to help promote intervertebral body fusion. The superior and inferior surfaces have teeth to assist in the interface with the vertebral endplates to help prevent rotation and/or migration. Additionally, the implants incorporate a titanium alloy (6AL-4V-ELI per ASTM F-136) anterior fixation plate which has integrated screw holes to allow for placement of four titanium alloy screws and a titanium alloy lock plate that anchor the implant to the adjacent vertebrae. The implants are available in a range of sizes and footprints to suit the individual pathology and anatomical conditions of the patient.

All implants are intended for single use only and should not be reused under any circumstances. **Do not use any of the DYNA-LINK Stand-Alone Anterior Lumbar System components with components from any other system or manufacturer. The components should never be reused under any circumstances.**

Indications, Contraindications, and Possible Adverse Effects.
Indications:
The DYNA-LINK Stand-Alone Anterior Lumbar System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment. This device is intended to be used with autogenous bone graft.

The DYNA-LINK Stand-Alone Anterior Lumbar System is intended for use with four titanium alloy screws which are provided with the system. If the physician chooses to use fewer than four of the provided screws, then a supplemental internal spinal fixation system that is cleared for use in the lumbosacral spine must be used.

Contraindications:
Contraindications include, but are not limited to:
1. Active systemic infection of infection local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness, alcoholism, drug abuse.
7. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
9. Suspected or documented material allergy or intolerance.
10. Any case not needing a bone graft and fusion or where fracture healing is not required.
11. Any case requiring the mixing of metals from different components.
12. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
13. Any condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis
14. Any case not described in the Indications.
15. Any patient unwilling to cooperate with the post-operative instructions.
16. Any time implant utilization would interfere with anatomical structures or expected physiological performance, or if the patient has grossly distorted anatomy caused by congenital abnormalities.
17. Symptomatic cardiac disease.
18. Spondylolisthesis of Grade II or greater.
19. Systemic or terminal illness.
20. Prior fusion at the levels to be treated.

Potential Adverse Events:
A listing of possible adverse events includes, but is not limited to:
1. Early or late loosening of any or all of the components.
2. Disassembly, loosening, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears.
8. Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
9. Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
10. Loss of bowel and/or bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
13. Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery
14. Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
15. Graft donor site complications including pain, fracture, or wound healing problems.
16. Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
17. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
18. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
19. Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
20. Change in mental status.
21. Non-union (or pseudarthrosis). Delayed union. Mal-union.
22. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function.
23. Inability to perform the activities of daily living.
24. Paralysis
25. Death
Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

Warnings and Precautions:
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. The DYNA-LINK Stand-Alone Anterior Lumbar System is only an implant used for the correction and stabilization of the spine. This system is intended to be used to augment the development of a spinal fusion by providing temporary stabilization while a solid fusion mass forms. This device system is not intended to be the sole means of spinal support. The use of autogenous bone graft must be part of the spinal fusion procedure in which the DYNA-LINK Stand-Alone Anterior Lumbar System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the DYNA-LINK Stand-Alone Anterior Lumbar System by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.

The DYNA-LINK Stand-Alone Anterior Lumbar System has not been evaluated for safety and compatibility in the MR environment. The DYNA-LINK Stand-Alone Anterior Lumbar System has not been tested for heating or migration in the MR environment.

WARNING: The implantation of intervertebral body fusion devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

WARNING: Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION: The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established.

CAUTION: The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Based on device testing results, the physician should always consider a variety of patient conditions including but not limited to the levels of implantation, patient weight, and patient activity level, which may have an impact on the performance of the intervertebral body fusion device.

CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

PI-0006-E

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Other preoperative, intraoperative, and postoperative warnings are as follows:

Implant Selection:
The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Preoperative:
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The DYNA-LINK Stand-Alone Anterior Lumbar System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative:
1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
3. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
4. Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.
5. Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.
6. Before closing the soft tissues, all of the devices should be securely seated.
7. Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.

Postoperative:
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of fatigue and/or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient 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. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
3. The patient 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.
4. If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
5. The DYNA-LINK Stand-Alone Anterior Lumbar System implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process while a solid fusion forms. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal should be followed by adequate postoperative management to avoid fracture.
6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the DYNA-LINK Stand-Alone Anterior Lumbar System components should ever be reused under any circumstances.

Packaging:
Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to LIFE SPINE.

Cleaning and Decontamination:
Precleaning:

Remove debris from instruments with sterile water and sponge during the procedure to prevent drying of blood and bodily fluids. Blood and bodily fluids are highly corrosive and can produce stains that are difficult to remove.

Cleaning:
All instruments and trays must first be cleaned before sterilization and introduction into a sterile surgical field.

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment. A room temperature enzymatic cleaner bath (soak) or a solution of room temperature water and neutral pH detergent are effective in removing organic material from instruments. Use distilled (demineralized) water if possible. Instruments should be fully submerged for at least 10 minutes.

Instruments and trays must be thoroughly cleaned. Be sure dissimilar metal instruments are separated. Immerse instruments fully opened and flush all cannulas with room temperature water until rinse water runs clear. Use a small brush to remove soil from all surfaces of the instrument while fully immersed in the solution. Remove soil from hinges, jaws, tips, box locks, and ratchets. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments and trays. If there is any visual contamination, repeat the steps as necessary until the instruments and trays are visually clean. Rinse instruments and trays under running room temperature water for at least 1 minute to remove solutions.

If contamination is unable to be removed, return the instrument and/or tray to Life Spine in a sealed container clearly marked “contaminated.”

Instruments and trays should never be exposed to cleaning agents containing any peroxides.
Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Sterilization:
Unless noted otherwise on the package labeling, the DYNA-LINK Stand-Alone Anterior Lumbar System components are provided non-sterile. These products need to be steam sterilized by the hospital using the following method:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Gravity Displacement	270°F(132°C)	30 minutes	60 minutes
Method	**Cycle**	**Temperature**	**Exposure Time**	**Dry Time**
Steam	Prevacuum	270°F(132°C)	4 minutes	60 minutes

The Sterility Assurance Level (SAL) is 1×10^{-6}, via the indicated methods.

No claims of pyrogenicity are made.

Remove all packaging materials prior to sterilization. Do not stack trays during sterilization. Use only sterile products in the operative field.

Always immediately re-sterilize all implants, instruments, and trays used in surgery. This process must be performed before handling or (if applicable) returning to Life Spine.

This gravity displacement sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user’s responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Product Complaints:
Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, LIFE SPINE. Further, if any of the implanted DYNA-LINK Stand-Alone Anterior Lumbar System component(s) ever "malfunctions", (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any LIFE SPINE product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Further Information:
Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact:

Life Spine
13951 S. Quality Drive
Huntley, IL 60142
USA

Tel: 847-884-6117
Fax: 847-884-6118
www.lifespine.com

PI-0006-E

Life Spine
13951 S. Quality Drive
Huntley, IL 60142
Phone (847) 884-6117
Fax (847) 884-6118
www.lifespine.com

U.S. & Foreign Patents Pending
Doc. No. STG-071212 Rev. C