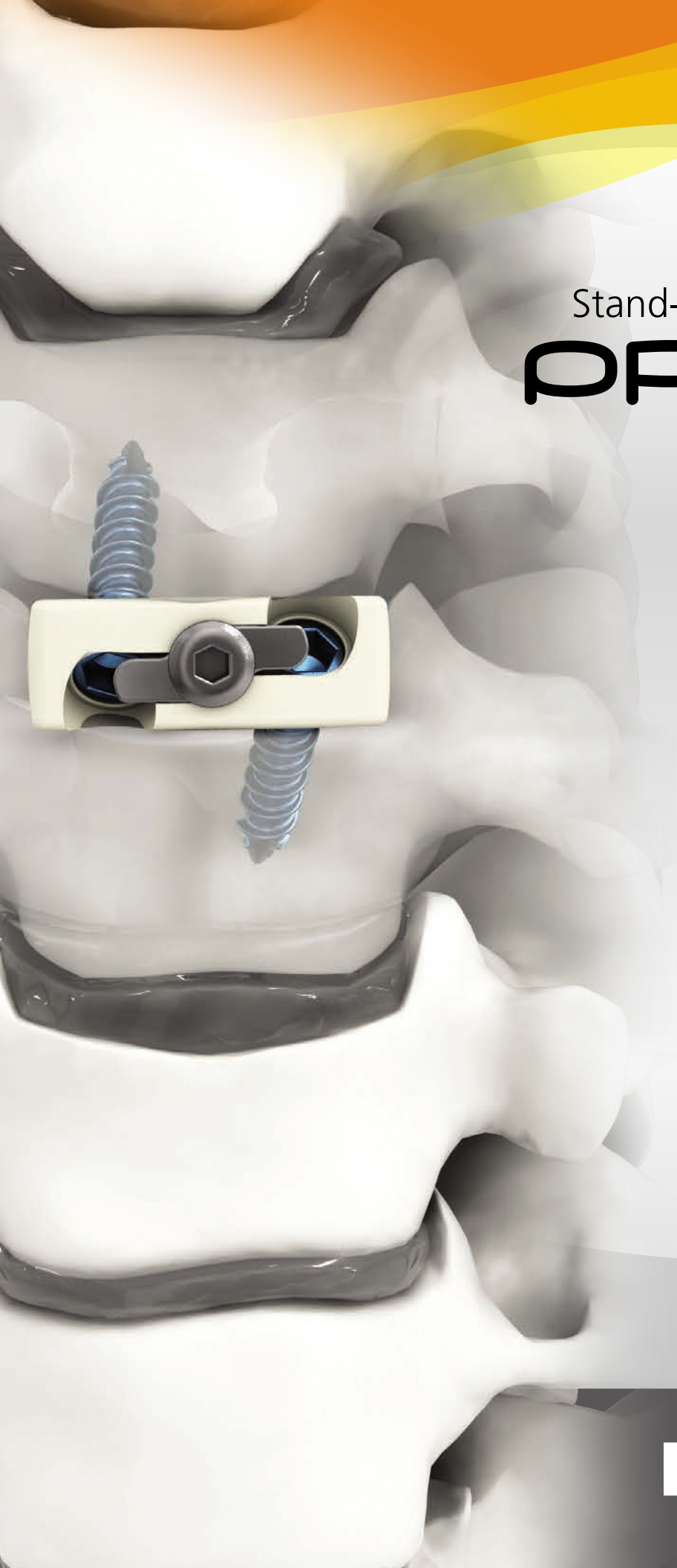


Stand-Alone Cervical Spacer System

PRO-LINK®

SURGICAL TECHNIQUE GUIDE

LifeSpine® Designs For Life.®

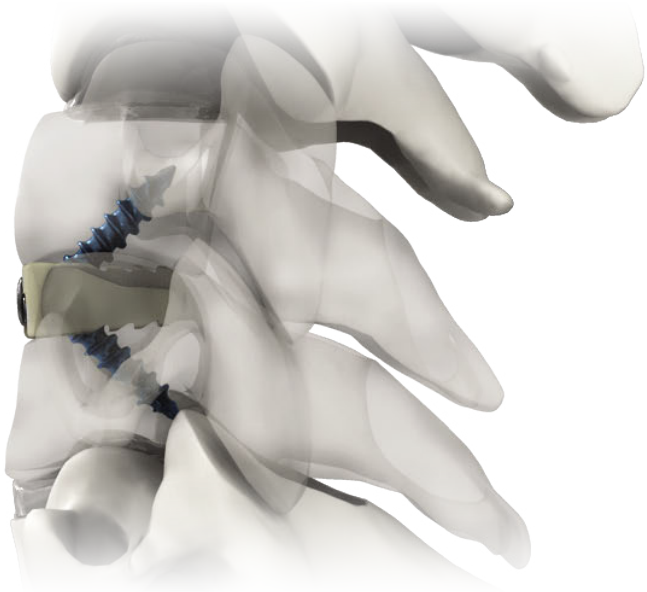
Stand-Alone Cervical Spacer System

PRO-LINK®

CONTENTS

PRO-LINK Stand-Alone Cervical Spacer System

The PRO-LINK Stand-Alone Cervical Spacers are designed with a large, open graft area for maximum bone graft capacity. The spacers allow fusion at adjacent segments without the removal of an existing anterior cervical plate. The low-profile locking plate provides protection against screw backout without disturbing surrounding soft tissue.

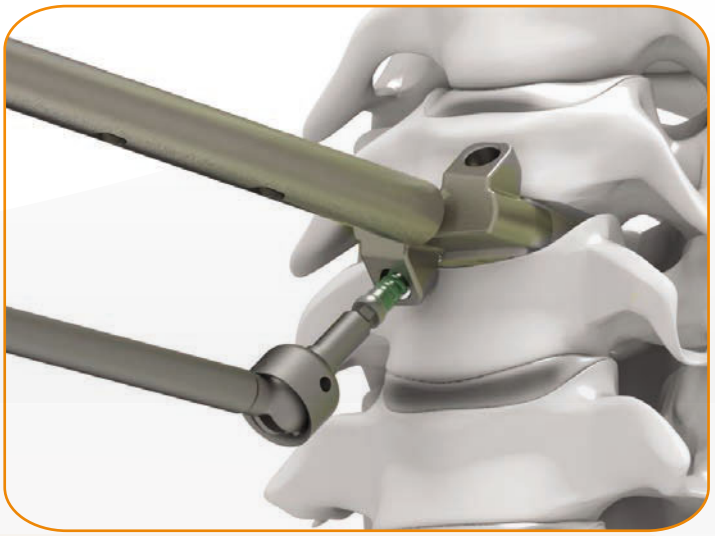


Low-Profile Titanium Locking Plate

» Provides protection against screw backout

Intuitive Instrumentation

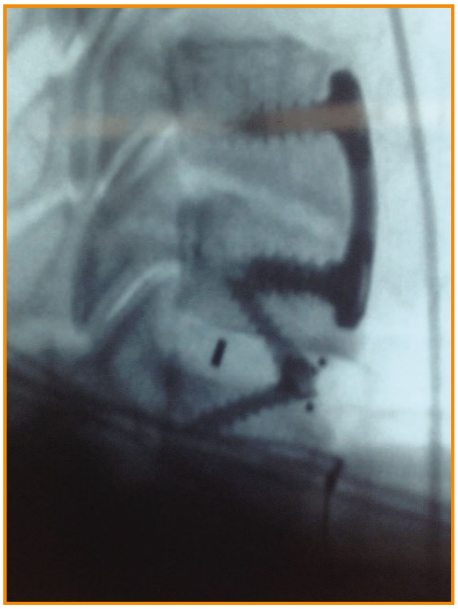
» Provide intraoperative assurance and reliability



Aggressive Self-Drilling/Self-Tapping Screws

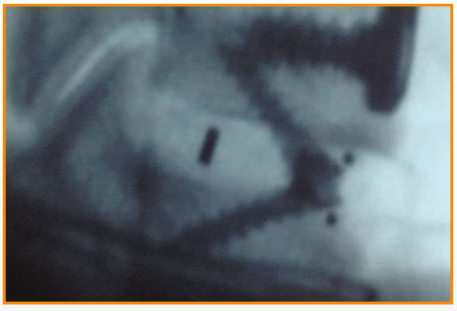
» Eliminate the need for drilling or tapping and reduce intra-operative time

Post Operative X-Ray



Radiopaque Tantalum Markers

» Improve intra-operative visualization



Titanium Screw Pockets

» Prevent advancement of the screw into the graft space

PRO-LINK Implants

Lordotic Implants	20-1613-705	16mm x 13mm x 5mm, 7°
	20-1613-706	16mm x 13mm x 6mm, 7°
	20-1613-707	16mm x 13mm x 7mm, 7°
	20-1613-708	16mm x 13mm x 8mm, 7°
	23-1613-709	16mm x 13mm x 9mm, 7°
	23-1613-710	16mm x 13mm x 10mm, 7°
	23-1613-711	16mm x 13mm x 11mm, 7°
	23-1613-712	16mm x 13mm x 12mm, 7°

Parallel Implants	21-1613-05*	16mm x 13mm x 5mm, 0°
	21-1613-06*	16mm x 13mm x 6mm, 0°
	21-1613-07*	16mm x 13mm x 7mm, 0°
	21-1613-08*	16mm x 13mm x 8mm, 0°
	24-1613-09*	16mm x 13mm x 9mm, 0°
	24-1613-10*	16mm x 13mm x 10mm, 0°
	24-1613-11*	16mm x 13mm x 11mm, 0°
	24-1613-12*	16mm x 13mm x 12mm, 0°

Fixed Angle Screws

129-110	3mm x 10mm
129-112	3mm x 12mm
129-114	3mm x 14mm

Rescue Fixed Angle Screws

129-310	3.5mm x 10mm
129-312	3.5mm x 12mm
129-314	3.5mm x 14mm

Variable Angle Screws

129-010	3mm x 10mm
129-012	3mm x 12mm
129-014	3mm x 14mm

Rescue Variable Angle Screws

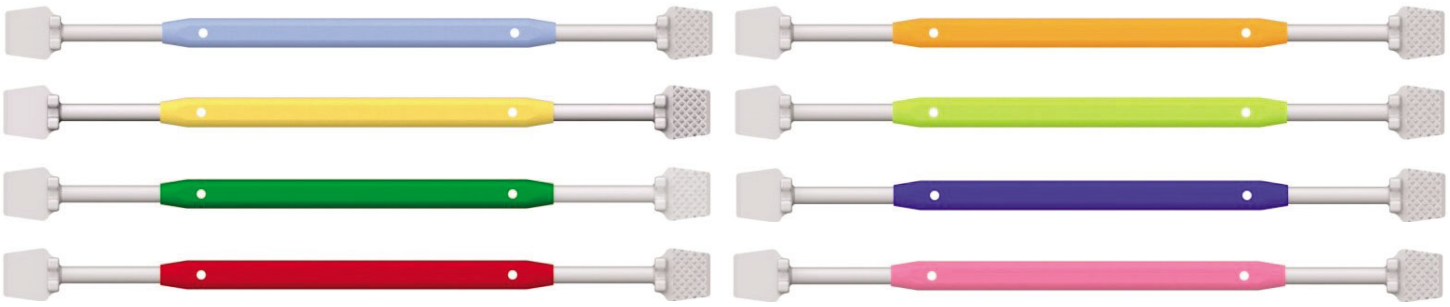
129-210	3.5mm x 10mm
129-212	3.5mm x 12mm
129-214	3.5mm x 14mm

Lock Plate

129-002	Lock Plate

PRO-LINK Standard Instrumentation

Instruments available for use with the PRO-LINK Stand-Alone Cervical Spacer System.



16mm x 13mm Rasp/Trial 7°, 5mm - 12mm w/stop

16mm x 13mm Rasp/Trial 0°, 5mm - 12mm w/stop*

Interbody Installer

Dual Barrel Drill Guide/Installer Sizes 5-8

Dual Barrel Drill Guide/Installer Sizes 9-12

Cervical Graft Packing Tool

Cervical Tamp

Cervical Graft Packing Block

*Available by Request Only

PRO-LINK Standard Instrumentation

Instruments available for use with the PRO-LINK Stand-Alone Cervical Spacer System.

AO Ratcheting Straight Handle

Centering Bent Awl

Adjustable Awl

Bent Awl

Straight Drill, 3.0mm

45° Angulating Drill, 3.0mm

Fixed Angle Drill, 3.0mm

Straight Tap, 3.0mm

45° Angulating Tap, 3.0mm

Fixed Angle Tap, 3.0mm

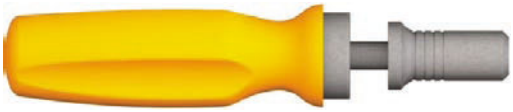
INSTRUMENTATION

2.5mm Hex Straight Screwdriver

2.5mm Hex 45° Angulating Screwdriver

2.5mm Hex Fixed Angle Screwdriver

Lock Plate Inserter



AO Torque Limiting Straight Handle, 3 in-lbs

Screw Removal Tool

Slotted Slap Hammer

PRO-LINK Surgical Technique

1. Preoperative Planning and Patient Positioning

Preoperative planning is critical in the preparation for spinal surgery. Prior to surgery, determine the surgical approach and approximate interbody size.

2. Exposure

Utilizing a standard surgical approach, expose the vertebral bodies to be fused. Prepare the fusion site following the appropriate technique for a given indication.

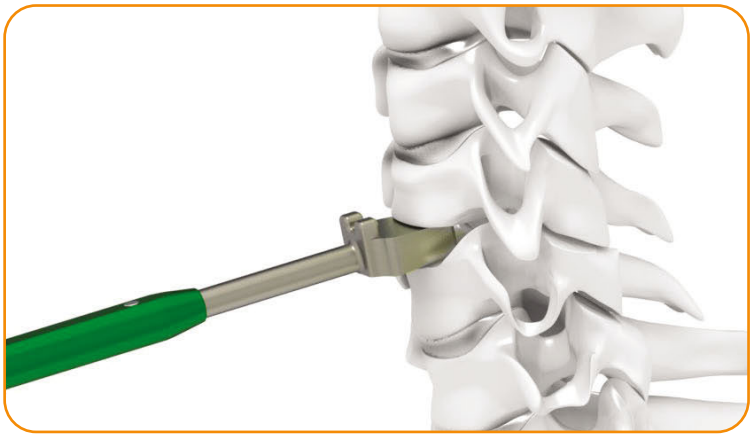
3. Endplate Preparation

Rasps 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 interbody and bone graft material.

4. Interbody Size Selection

Insert the smallest Trial first, moving to larger trials as needed. Each trial is color coded to differentiate size and should be used incrementally to determine the appropriate size of the interbody.

With the segment fully distracted, the Trial must fit securely between the endplates. A tight fit is desirable in order to achieve intervertebral height and segment stability. This can be confirmed with intraoperative imaging and tactile feedback.



NOTE: Rasps/Trials without stops are available upon request.

5. Loading Spacer to Installer

There are two options for interbody installation. The first option allows for freehand screw hole preparation (Interbody Installer). The second option allows for an all in one installation with an integrated guide (Dual Barrel Drill Guide/Installer).

The interbody can be loaded directly from the interbody caddy by placing the two prongs of the installer into the corresponding holes of the interbody.

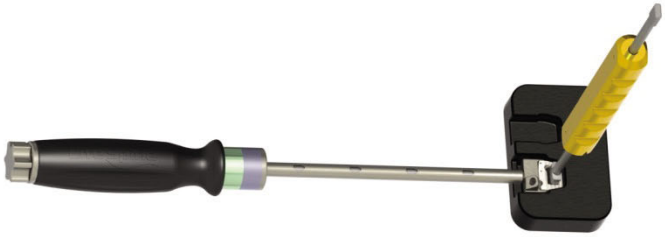
Turn the knob on the end of the Installer clockwise, screwing the central threads of the Installer into the interbody.

NOTE: Use caution when tightening to avoid stripping the interbody threads and/or difficulty removing the interbody from the Installer.

6. Graft Packing

Place the interbody into the appropriate window of the Cervical Graft Packing Block. Firmly pack autogenous bone graft material into the graft area of the interbody using the Cervical Graft Packing Tool.

To ensure optimal contact with endplates, pack the interbody until the graft material overflows from the graft area.



7. Interbody Insertion

With the interbody attached to the Installer, insert the interbody into the distracted intervertebral space. If necessary, the Installer can be tapped with the Slotted Slap Hammer to advance the interbody into the intervertebral space.

The interbody should be placed slightly recessed, up to 2mm from the anterior lip of the vertebral body.

NOTE: It is recommended to release distraction while impacting the Installer.

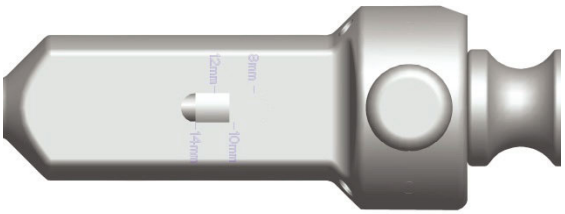
NOTE: The Slotted Slap Hammer can also be used in conjunction with the Installer to remove or reposition the interbody.

8. Verify Spacer Position

Confirm placement of the interbody with AP and lateral fluoroscopy. If the interbody requires further adjustment, use the Cervical Tamp and Slotted Slap Hammer to manipulate the interbody into the final position.

RADIOGRAPHIC MARKER PLACEMENT

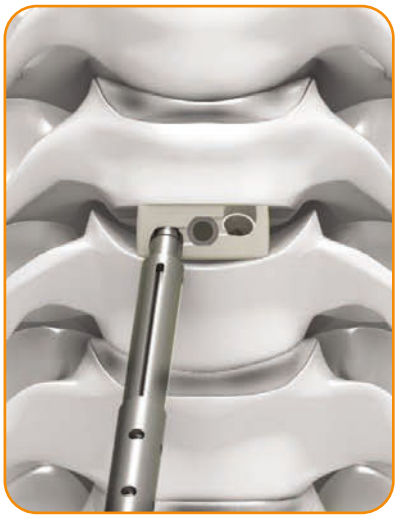
- 1.25mm from the back wall (x1)
- 1.25mm from the front wall (x2)



9. Screw Hole Preparation – Awl

Adjustable Awl

Determine the entry point and trajectory for the screw. The optimal angulation for the screws are 45° cephalad/caudal and 8° medially.



The Adjustable Awl allows for preparation of different pilot hole depths. To set the Adjustable Awl depth, depress the adjustment button and slide the depth stop to the desired depth as indicated on the calibrated depth stop.

Insert the Adjustable Awl at the appropriate angle into the screw pocket of the interbody and push down while simultaneously twisting the handle.

Remove the Adjustable Awl, maintaining alignment of the hole and plate.

Bent Awl

Insert the Bent Awl at the appropriate angle within the guide of the installer and push down on the handle. The depth of the Bent Awl is equal to the depth of the shortest screw length when placed in the interbody.

Remove the Bent Awl maintaining alignment of the hole and plate.

NOTE: Intraoperative imaging should be used to confirm awl trajectory.

NOTE: The Centering Bent Awl can also be used for screw hole preparation.

IMPORTANT: Exercise extreme caution that the awl does not move the interbody during pilot hole preparation. For particularly hard bone, drilling and tapping is recommended to minimize interbody movement.

10. Screw Hole Preparation – Drill and Tap

Straight, 45° Angulating, and Fixed Angle Drill

The Straight, 45° Angulating, and Fixed Angle Drill, 3.0mm can be used with the Interbody Installer or the Dual Barrel Drill Guide/Installers.

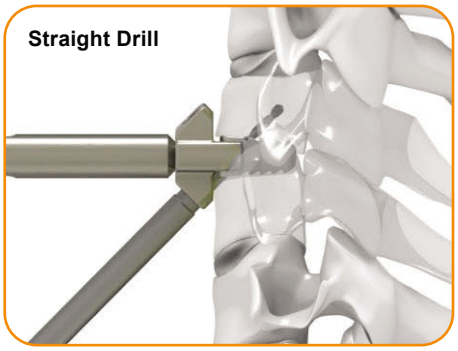
Connect the Drill to an AO Ratcheting Straight Handle .

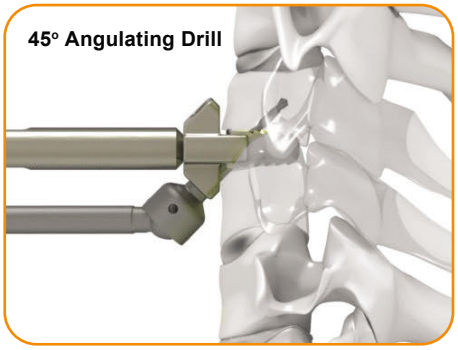
Insert the tip of the Drill into the guide at the appropriate trajectory. Advance the drill bit in a clockwise direction until the stop on the drill reaches the guide. The stop provides the desired drill depth, which is equal to the depth of the shortest screw length when placed in the interbody.

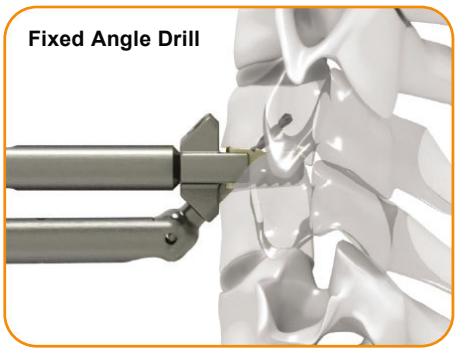
Remove the Drill, maintaining alignment of the hole and plate.

NOTE: Intraoperative imaging should be used to confirm Drill trajectory.

IMPORTANT: Exercise extreme caution that the Drill does not move the interbody during pilot hole preparation.







Straight, 45° Angulating, and Fixed Angle Tap

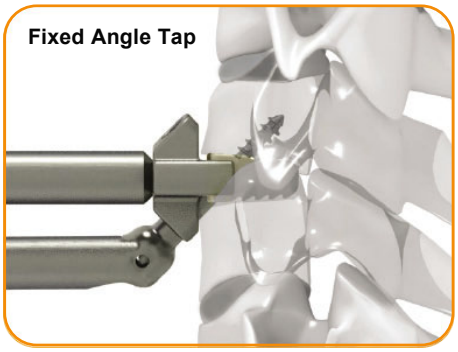
The Straight, 45° Angulating, and Fixed Angle Tap, 3.0mm can be used with the Interbody Installer or the Dual Barrel Drill Guide/Installers.

Connect the Tap to an AO Ratcheting Straight Handle.

Insert the tip of the Tap into the guide at the appropriate trajectory. Advance the tap in a clockwise direction until the stop on the tap reaches the guide. The stop provides the desired tap depth, which is equal to the depth of the shortest screw length when placed in the interbody.

Remove the Tap, maintaining alignment of the hole and plate.

NOTE: Intraoperative imaging should be used to confirm Tap trajectory.



IMPORTANT: Exercise extreme caution that the Tap does not move the interbody during pilot hole preparation.

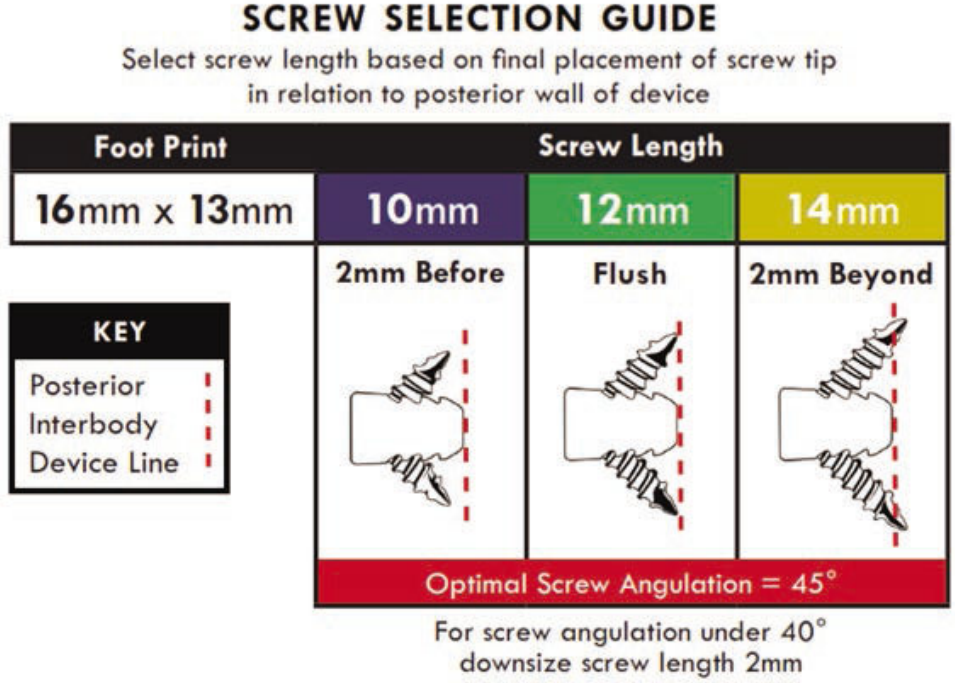
11. Screw Length Selection

In conjunction with preoperative and intraoperative findings, refer to the Screw Selection Guide to determine appropriate screw length.

Select the screw length based on desired final placement of the screw tip in relation to the Posterior Interbody Device Line .

Posterior Interbody Device Line:

A line tangent to the most posterior aspect of the Pro-Link Stand-Alone Cervical Interbody on the transverse view.



Bone Screws are color coded to differentiate the following:

- Diameter 3.0mm or 3.5mm
- Length: 10mm – 14mm in 2mm increments

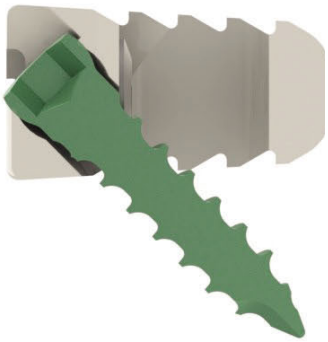
Pro-Link Screw head colors:

- Fixed Angle 3.0mm – Sea Foam Green
- Fixed Angle 3.5mm (Rescue) – Gray
- Variable Angle 3.0mm – Blue
- Variable Angle 3.5mm (Rescue) – Magenta

Pro-Link Screw shaft colors:

- 10mm – Vector Purple
- 12mm – Green
- 14mm – Gold

12. Screw Insertion

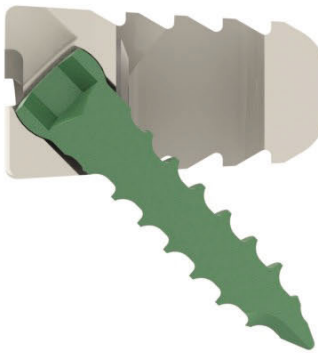


All screws are self-drilling/self-tapping to streamline the surgical procedure by minimizing the number of surgical steps associated with screw implantation.

The 2.5mm Hex Straight, 45° Angulating, and Fixed Angle Screwdriver can be used with the Interbody Installer or the Dual Barrel Drill Guide/Installers.

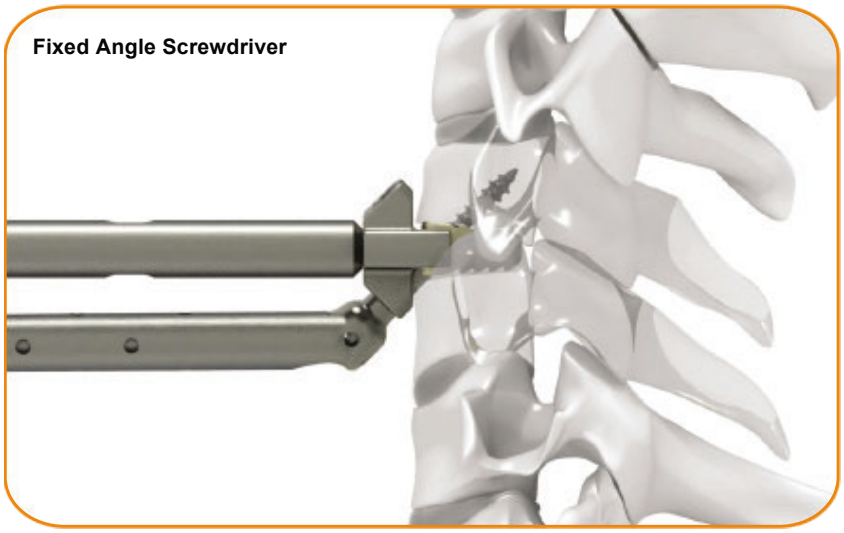
Place the selected screw onto the Screwdriver by pushing the distal tip of the Screwdriver forcefully into the selected screw while the screw is in the caddy. The tip of the Screwdriver is designed to retain the screw securely for implantation.

Insert the bone screw into the prepared pilot hole until the screw head is slightly above the integrated screw capture within the bone screw hole. Do not advance the screw head past the integrated screw capture within the screw pocket at this time.



After confirmation of bone screw trajectories with intraoperative imaging, use the Screwdriver to perform final tightening while advancing the head of the bone screw past the integrated screw capture within the screw pocket.

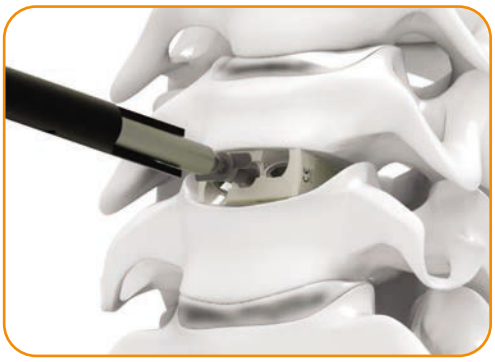
IMPORTANT: Confirm bone screw trajectories with intraoperative imaging PRIOR to advancement and final tightening of screw heads below the integrated screw capture within the screw pocket.



13. Lock Plate Insertion

The low-profile Lock Plate helps prevent screw back out. The Lock Plate is a two piece component. The center screw rotates independently from the plate.

The Lock Plate Inserter is used to securely retain and insert the Lock Plate directly from the screw caddy. Retract the external sleeve of the Lock Plate Inserter to expose the hex Inserter tip. Place the Lock Plate onto the Lock Plate Inserter by pushing the distal tip of the Inserter forcefully into the hex feature of the Lock Plate while in the screw caddy.



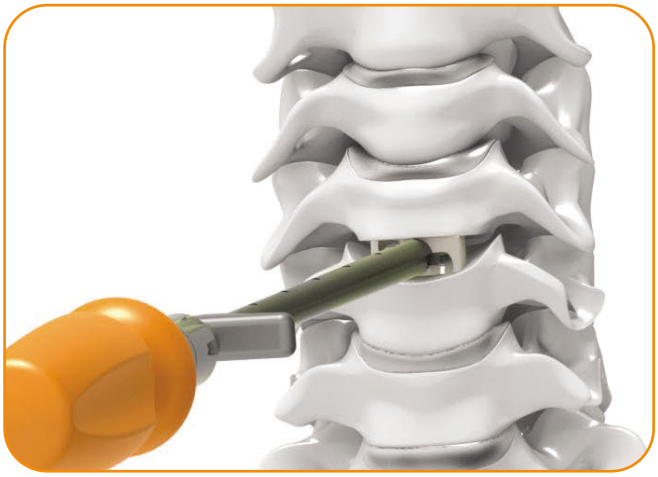
While holding the external sleeve in the retracted position, thread the Lock Plate screw into the threaded hole of the interbody. Once the screw is partially seated, gently slide the external sleeve toward the Lock Plate to capture the Lock Plate within the anti-rotation features on the distal tip of the Inserter sleeve. The external sleeve on the Lock Plate Inserter prevents the Lock Plate from rotating during the insertion of the hex screw into the threaded hole of the interbody. Continue tightening the screw using caution to avoid stripping the interbody threads.

The Lock Plate should be positioned flush within the recessed channels on the anterior face of the interbody.

IMPORTANT: The Lock Plate should only be installed <u>after</u> confirmation of bone screw trajectories with intraoperative imaging and final tightening of the screw head below the integrated screw capture within the screw pocket.

IMPORTANT: The Lock Plate is <u>not</u> an optional system component.

14. Final Tightening



Attach the Lock Plate Inserter to the AO Torque Limiting Straight Handle, 3 in-lbs. Turn the AO Torque Limiting Straight Handle, 3 in-lbs clockwise until an audible click is heard and tension is released in the handle.

15. Removal/Revision

All implants can be removed by performing the insertion steps in reverse. If necessary, utilize the Slotted Slap Hammer with the Interbody Installer to remove the interbody following removal of the Lock Plate and Bone Screws.

- The Lock Plate Inserter is used for Lock Plate removal.
- The Screw Removal Tool is used to remove the integrated screw capture of the interbody and a 2.5mm Hex Screwdriver is used for Bone Screw Removal
- The Interbody Installer and Slotted Slap Hammer are used for interbody removal.

LIFE SPINE®

Pro-Link® Stand-Alone Cervical Spacer System

Standard Product Insert

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

IMPORTANT INFORMATION ON THE PRO-LINK STAND-ALONE CERVICAL SPACER SYSTEM

Description:
The PRO-LINK Stand-Alone Cervical Spacer System is intended to serve as an intervertebral body fusion device. The implant is available in a range of sizes and footprints to suit the individual pathology and anatomical conditions of the patient. It is fabricated and manufactured from Polyetheretherketone (PEEK-OPTIMA LT1) with tantalum markers and titanium pins (Ti 6Al-4V ELI). The implant is hollow to permit packing with autogenous 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 prevent rotation and/or migration. The implant has two pockets to permit placement of titanium bone screws (Ti 6Al-4V ELI) through the interbody to provide internal fixation. The implant also has one central threaded hole to permit the insertion of a titanium lock plate (Ti 6Al-4V ELI) to prevent screw back out.

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

Indications, Contraindications, and Possible Adverse Events

Indications:
The Pro-Link Stand-Alone Cervical Spacer System is intended to be used with the screws provided and requires no additional supplementary fixation.

The Pro-Link Stand-Alone Cervical Spacer System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. It is to be used in patients who have had at least six weeks of non-operative treatment. This device is intended to be used with autogenous bone graft.

Contraindications:
Contraindications include, but are not limited to:
1. Active systemic or local infection.
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.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteopenia 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 patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
12. Any condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis.
13. Any case not described in the Indications.
14. Any patient unwilling to cooperate with the post-operative instructions.
15. 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.
16. Symptomatic cardiac disease.
17. Systemic or terminal illness.
18. Prior fusion at the level 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. 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 PRO-LINK Stand-Alone Cervical Spacer System is an implant used solely 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 PRO-LINK Stand-Alone Cervical Spacer 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 PRO-LINK Stand-Alone Cervical Spacer 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. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery.

The PRO-LINK Stand-Alone Cervical Spacer System has not been evaluated for safety and compatibility in the MR environment. The PRO-LINK Stand-Alone Cervical Spacer System has not been tested for heating or migration in the MR environment.

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: 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 PRO-LINK Stand-Alone Cervical Spacer System components are not to be combined with the components from another manufacturer
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.
7. All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to all surgeries.

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.
6. 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.
7. Before closing the soft tissues, all of the devices should be securely seated.
8. Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.
9. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.

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. 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.
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 retrieved PRO-LINK Stand-Alone Cervical Spacer System components should ever be reused under any circumstances.

Packaging:
All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to all surgeries. 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 PRO-LINK Stand-Alone Cervical Spacer 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 manufacturer, Life Spine. Further, if any of the implanted PRO-LINK Stand-Alone Cervical Spacer 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 manufacturer 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 manufacturer 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, address, and the nature of the complaint.

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:

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