NEURO® STRUCTURES

Belvedere™

LATERAL PLATING SYSTEM

SURGICAL TECHNIQUE GUIDE

Made in the USA

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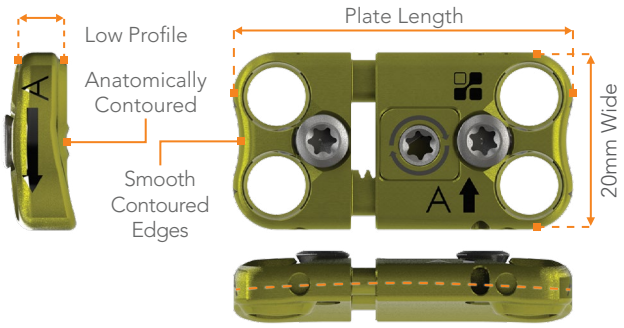
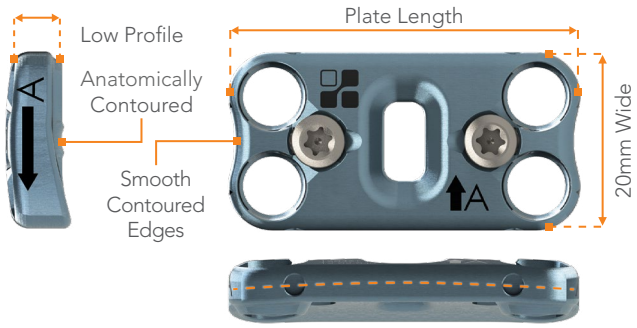
Belvedere™

This is intended as a guide only. There are multiple techniques for the delivery of Lateral Plate as with any surgical procedure. A surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for use insert for complete system description, indications and warning.

Adjustable Plate



Fixed Plate



Adjustable Length Plate

Plates	Length (mm)
I	36 – 39
II	38 – 42
III	41 – 49
IV	48 – 62
V	61 – 84
VI	83 – 106
VII	105 – 128

Fixed Length Plate

Plates	Length (mm)
	28, 30, 32, and 34
	35 – 135 in steps of 5

Screw Size

	Length (mm)										
Cortical Bone Screw	20	25	30	35	40	45	50	55	60	65	70
Bi-Cortical Bone Screw	20	25	30	35	40	45	50	55	60	65	70
Cannulated Bone Screw	20	25	30	35	40	45	50	55	60	65	70

Standard Sizes Non-Standard Sizes

Screws


Cortical Bone Screw

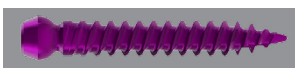

Bi-Cortical Bone Screw


Cannulated Bone Screw


5.0mm – *light blue*


5.5mm – *light green*


5.5mm – *light green*


5.0mm – *magenta*


6.5mm – *gold*


6.0mm – *gold*

1 Preparation & Sizing

Patient Positioning and O.R. Setup

The patient will be placed on a radiolucent, bendable surgical table in a direct lateral decubitus (90°) position.

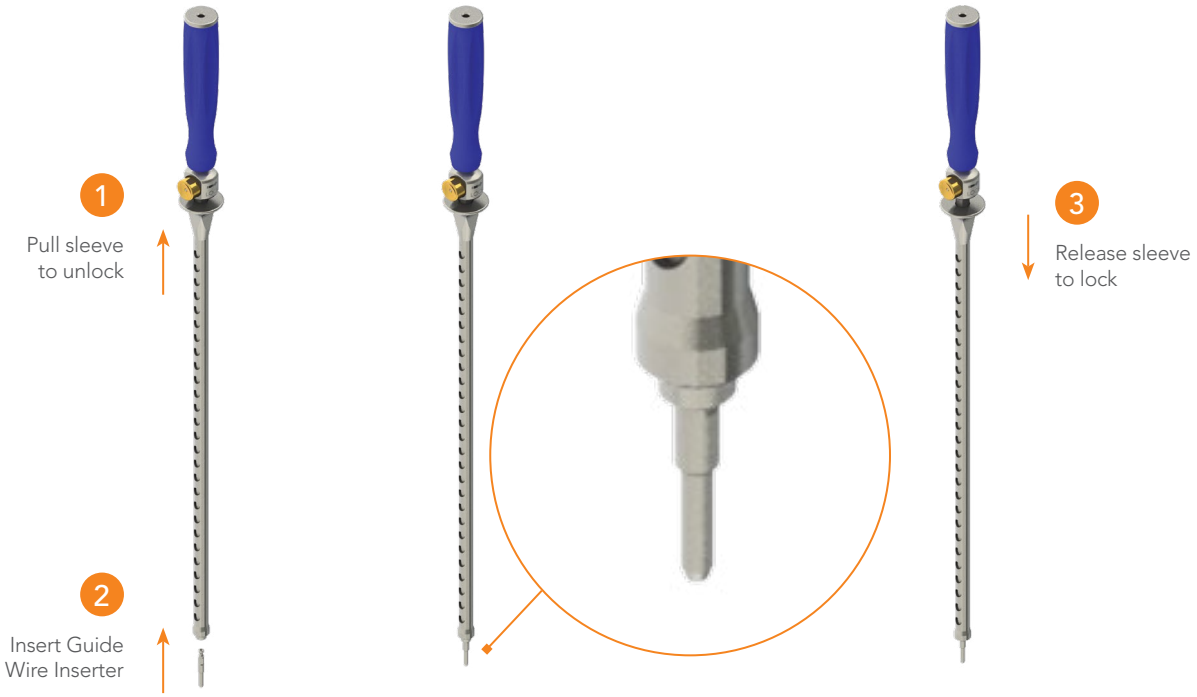
Prior to initiating the procedure, reconfirm a true A/P fluoroscopy image of the operative site with the C-arm at 0° and a true lateral image with the C-arm at 90°.

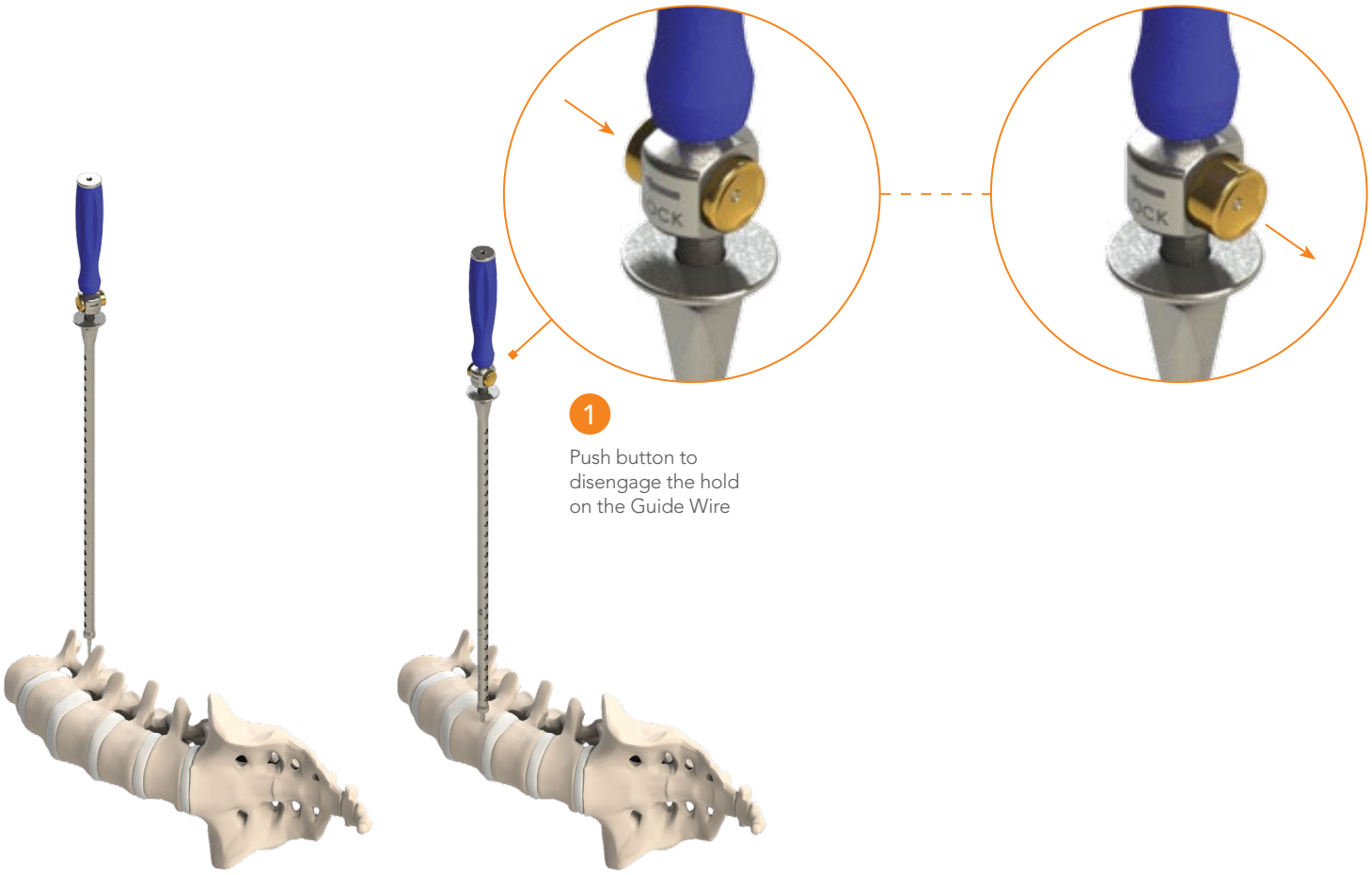
Osteophyte Removal (Optional)

The lateral surface of vertebral bodies is prepared as necessary, removing lateral osteophytes with an Osteophyte Removal Tool, pituitary, or Kerrison rongeur. Caution should be taken to remove only the necessary amount of the osteophyte.

Guide Wire Placement (Optional)

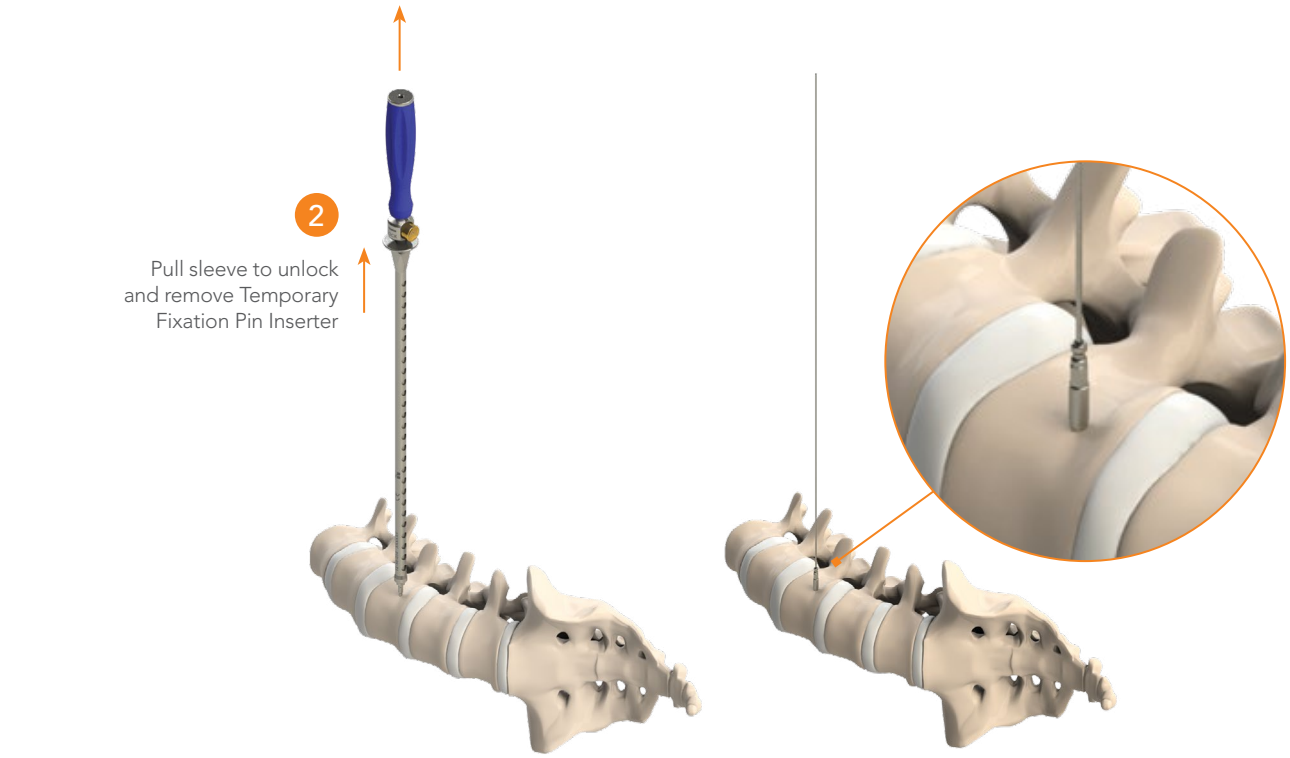
The Temporary Fixation Pin Inserter is used to place the Guide Wire Inserter approximately 3mm from the endplates. These instruments are designed to interface with the fixation hole(s) of the plate, conducting the plate into the desired position.





1

Push button to disengage the hold on the Guide Wire

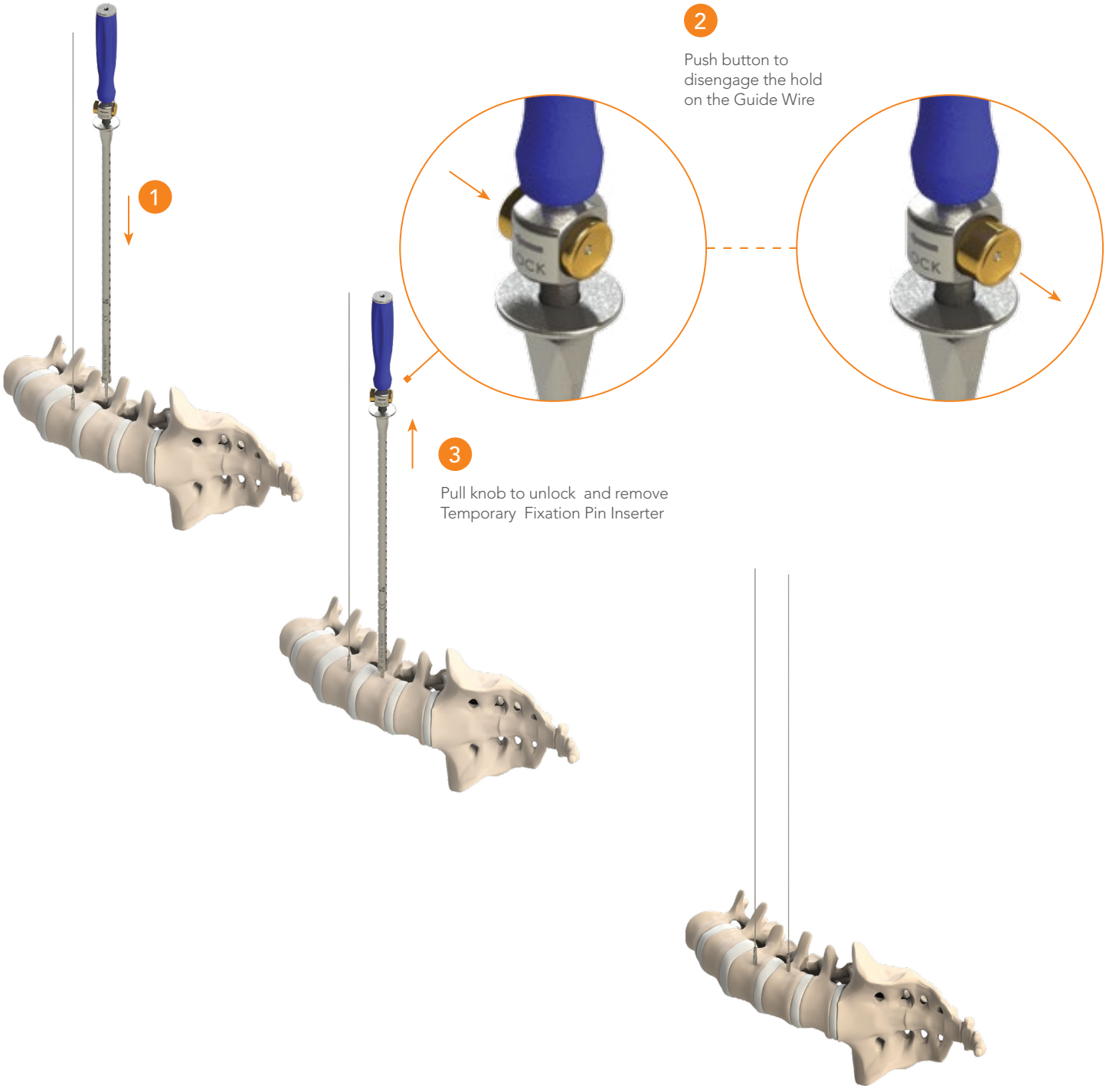


2

Pull sleeve to unlock and remove Temporary Fixation Pin Inserter

Guide Wire Placement (Optional)

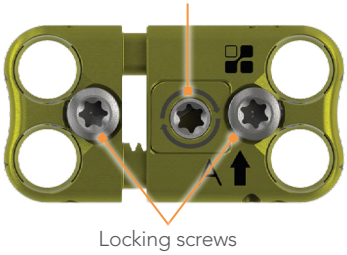
The Temporary Fixation Pin Inserter can then be used to place an additional Guide Wire Inserter. Repeat previous steps as needed to place additional guide wires.



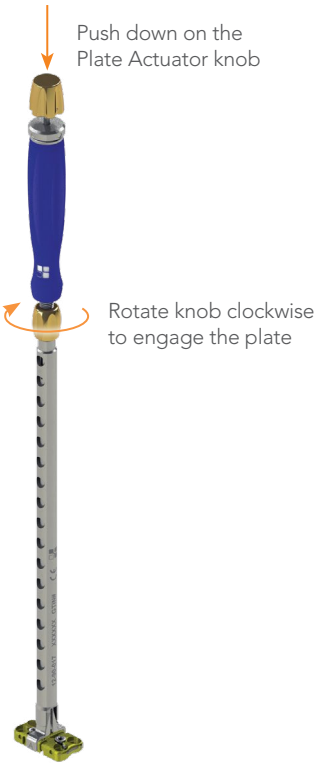
Simple Inserter

Select a fixed or adjustable length plate and attach the Simple Inserter.

The distal tip of the Simple Inserter is placed over the waist of the plate with the "A" on the Simple Inserter aligned with the corresponding arrow on the plate. Use downward pressure so the instrument is engaged around the plate. To tighten the Simple Inserter to the plate, rotate the mid-level knob clockwise until finger-tight.



Optional Fixed Plate



Align and insert Plate Actuator into the Plate Gear Driver prior to locking the Simple Inserter with the Plate

Adjustable Length Plate

If the adjustable length plate has been selected, the Simple Inserter can be used to adjust the plate to the length as needed.

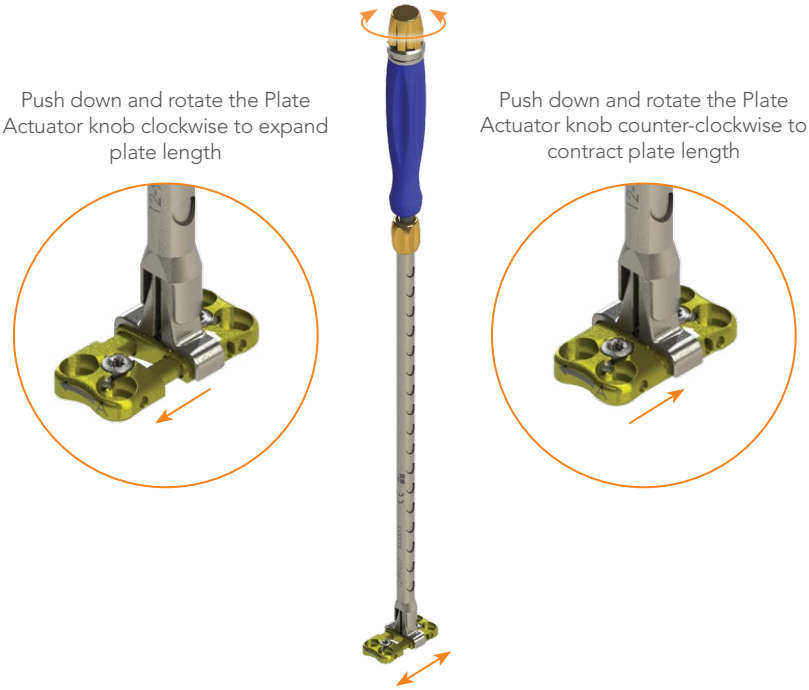
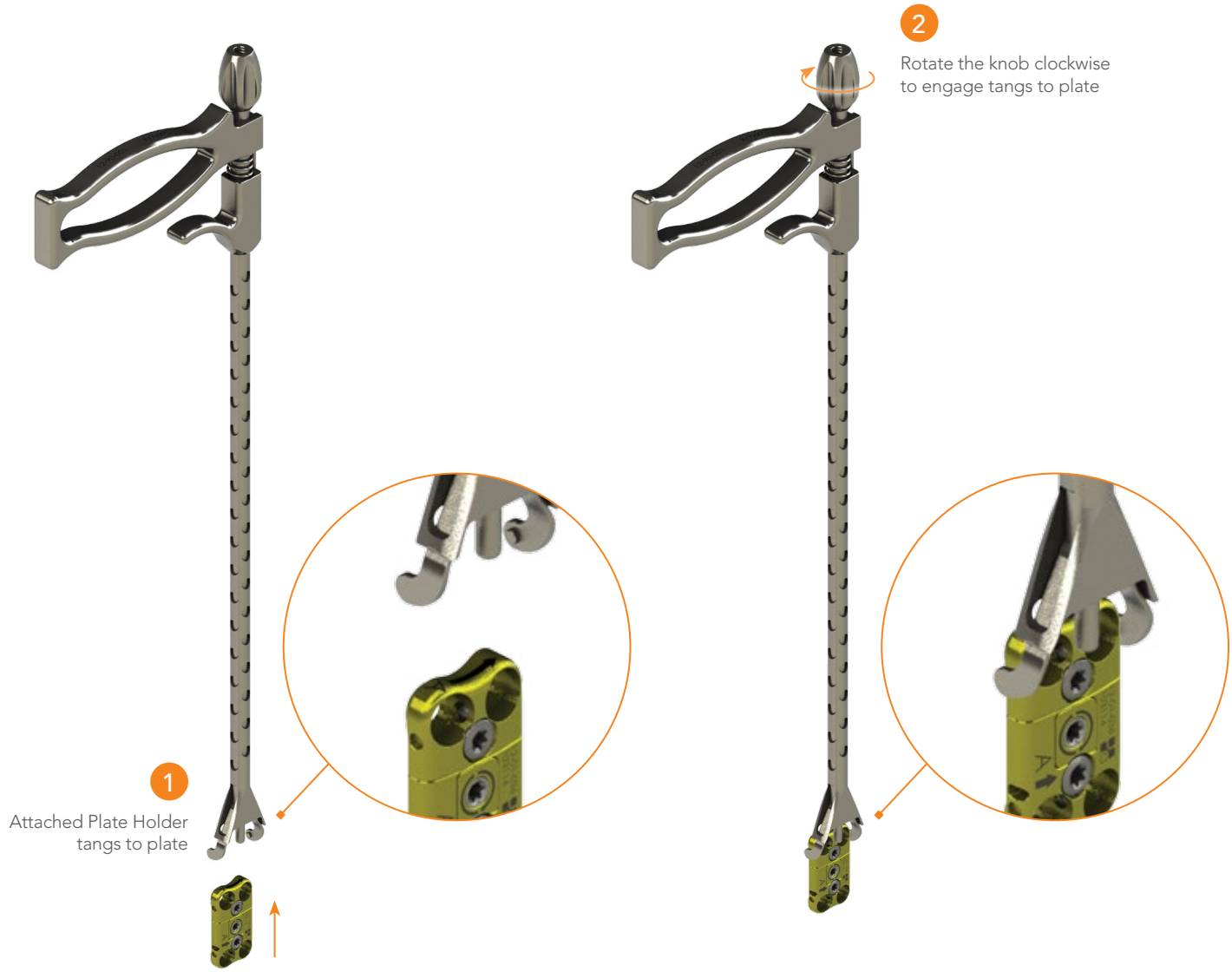


Plate Holder (Optional)

The Belvedere system comes with a Plate Holder as an alternative approach to the Simple Inserter.

Attach the Plate Holder to the plate by attaching the tangs into the tang holes on the plate. Rotate the knob on the Plate Holder clockwise to engage the plate.

Note: The Plate Holder also comes with the option with a drill guide.

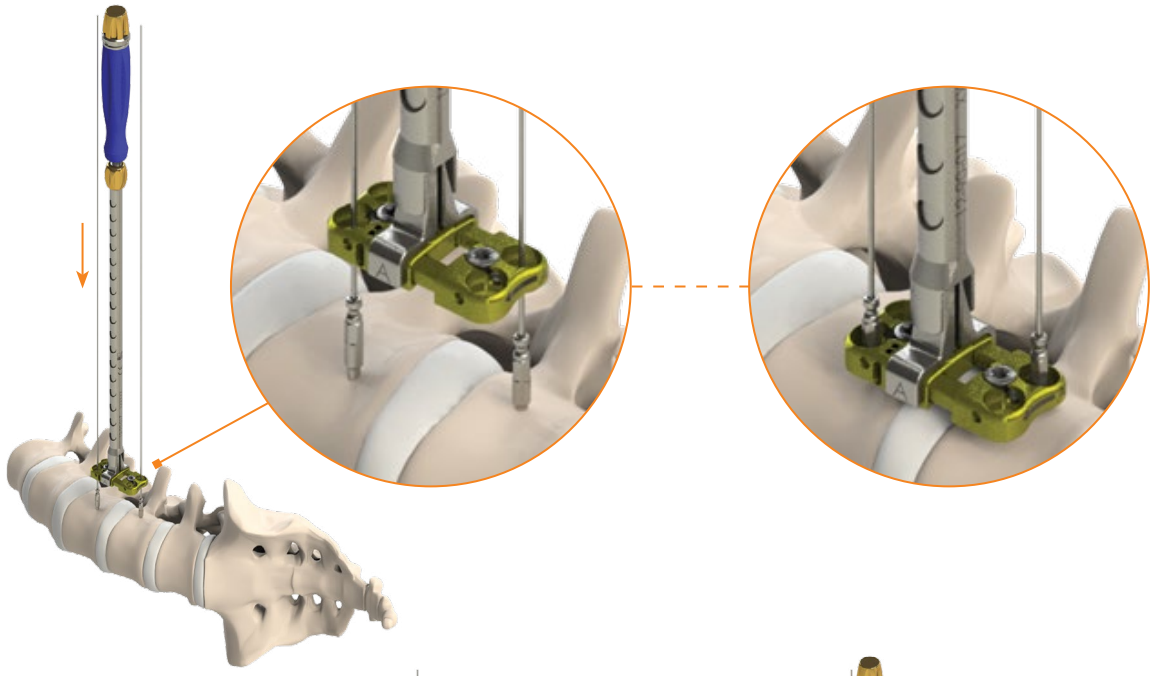


Simple Inserter

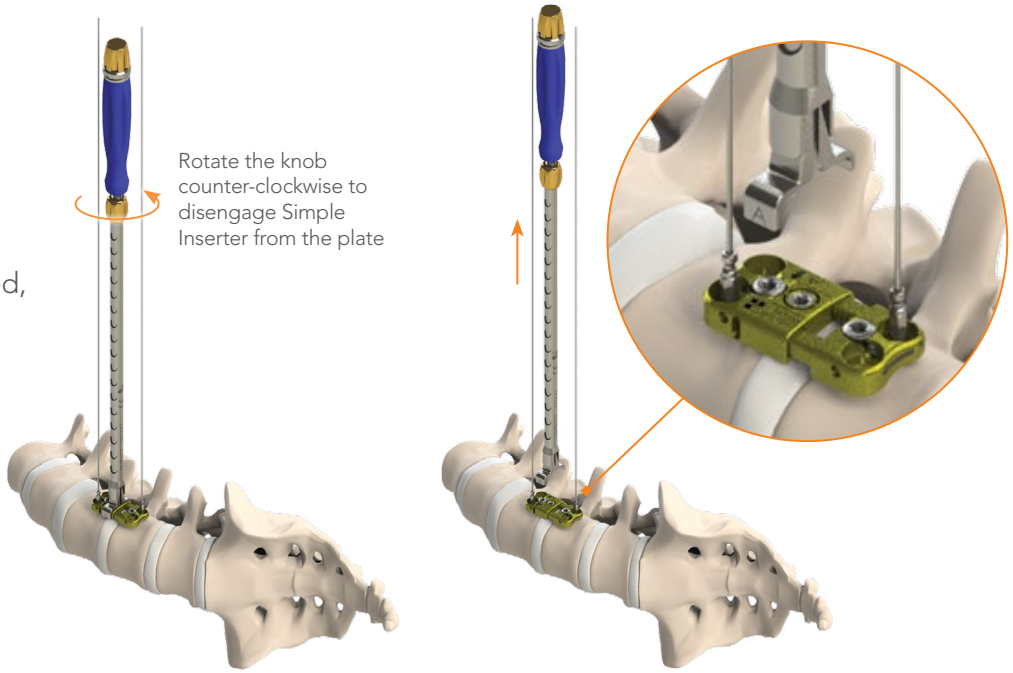
Insert the plate screw holes over the guide wire(s) and seat plate over the interbody implant. Position can be checked using fluoroscopy.

If using the adjustable plate, the plate length can be adjusted to help with insertion of plate over guide wires.

Note: The Plate should be oriented with primary fixation anterior as marked (A⬆) pointing to the anterior side.



Rotate the knob counter-clockwise to disengage Simple Inserter from the plate



Once the plate has been seated, remove the Simple Inserter.

Plate Holder (Optional)

If you are using the Plate Holder or Plate Holder with Drill Guide, the plate will be delivered in the vertical position. Upon insertion, pull the trigger to allow the plate to rotate and place the plate in the desired location. Position can be checked using fluoroscopy.

Note: The Plate should be oriented with primary fixation anterior as marked (A⬆) pointing to the anterior side.

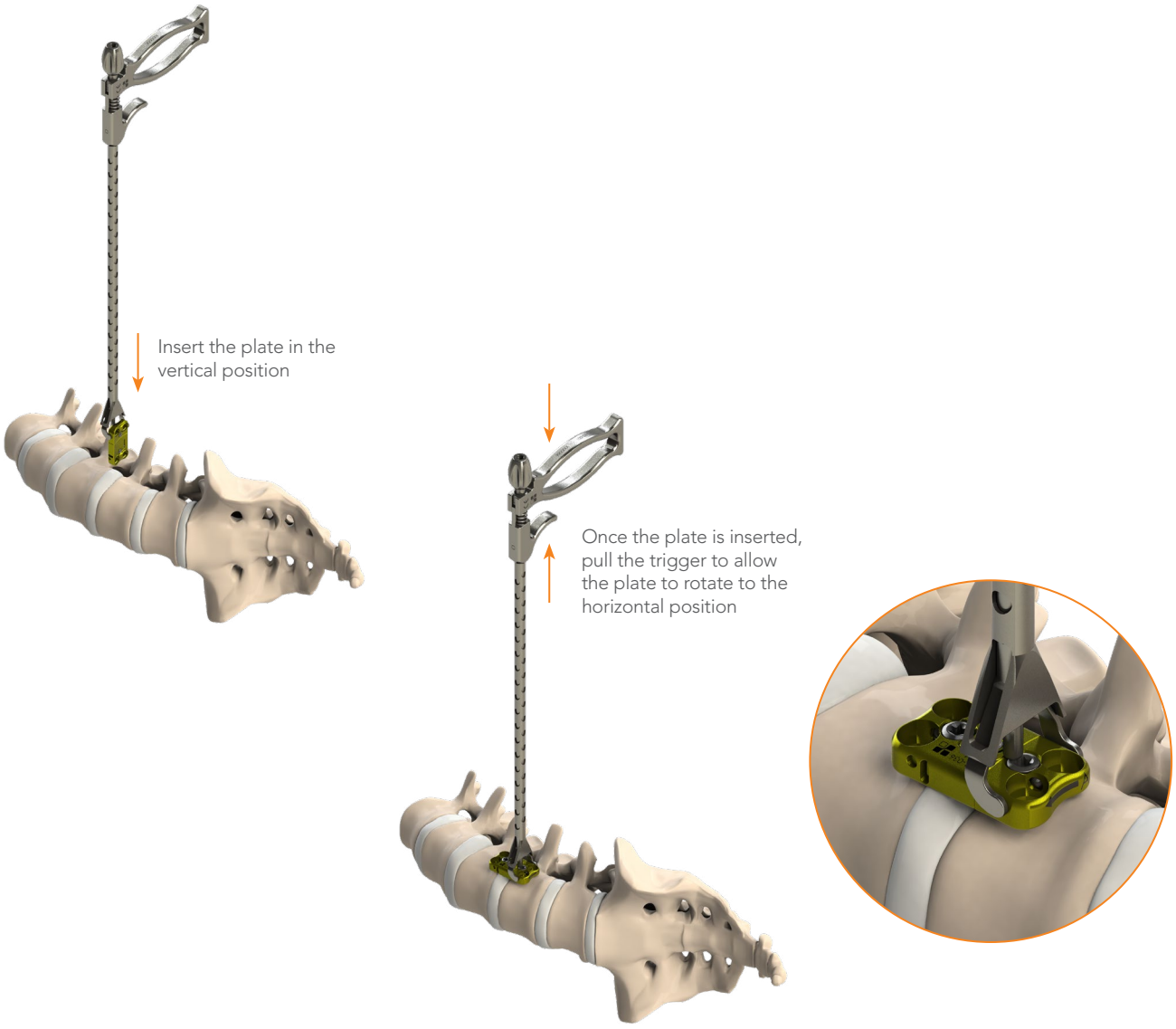


Plate Holder (Optional)

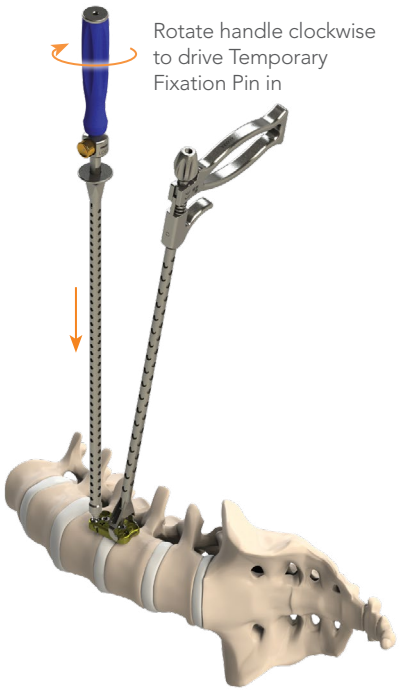
When using the Plate Holder or Plate Holder with Drill Guide, a short or long fixation pin can be used.

Temporary Fixation Pin

When using the Temporary Fixation Pin, attach the pin to the Temporary Fixation Pin

Insert the Temporary Fixation Pin into the screw hole and turn the handle clockwise to drive the Temporary Fixation Pin into the bone.

Once the Temporary Fixation Pin has been fully inserted, remove the Temporary Fixation Pin Inserter.



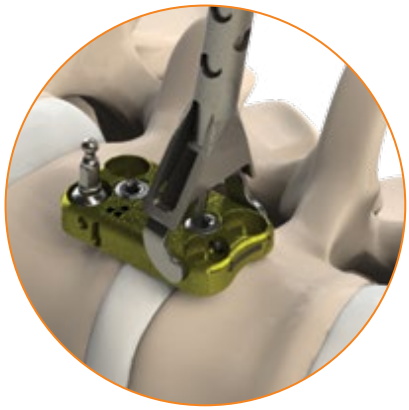


Plate Holder (Optional)

Temporary Long Fixation Pin

When using the Temporary Long Fixation Pin, attach the preferred handle.

Insert the Temporary Long Fixation Pin into the screw hole and turn the handle clockwise to drive the Temporary Long Fixation Pin into the bone.

Once the Temporary Long Fixation Pin has been fully inserted, remove the handle.

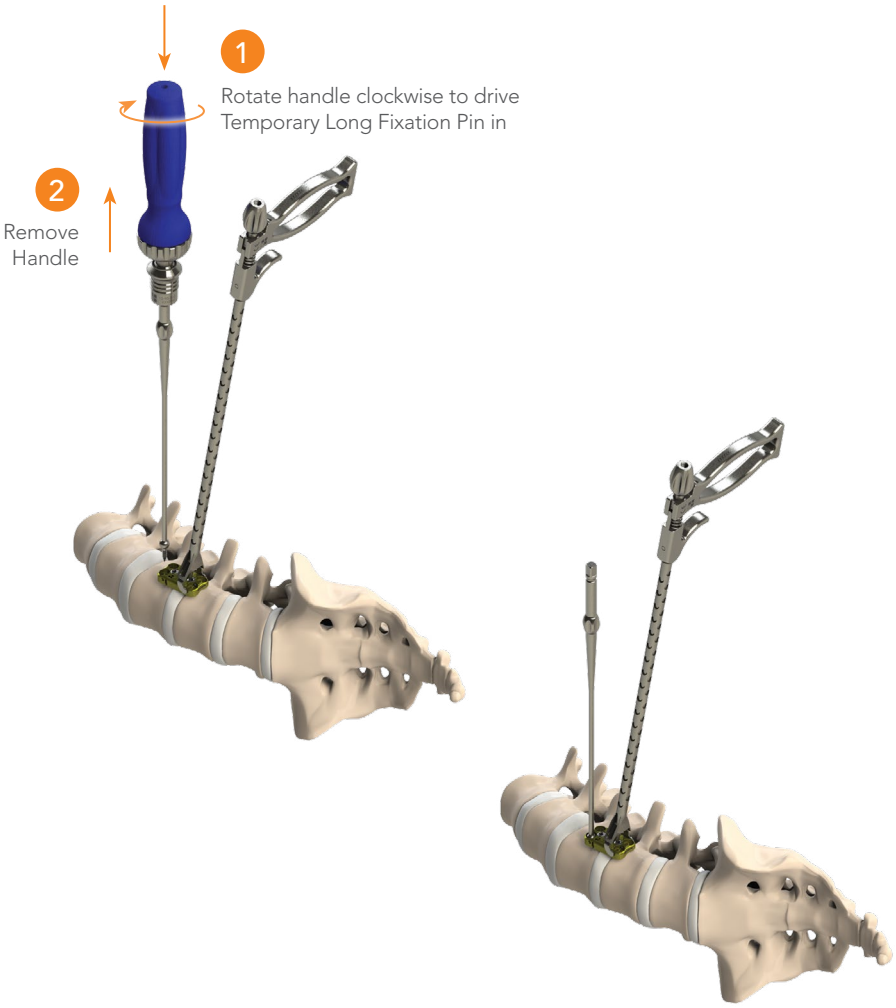
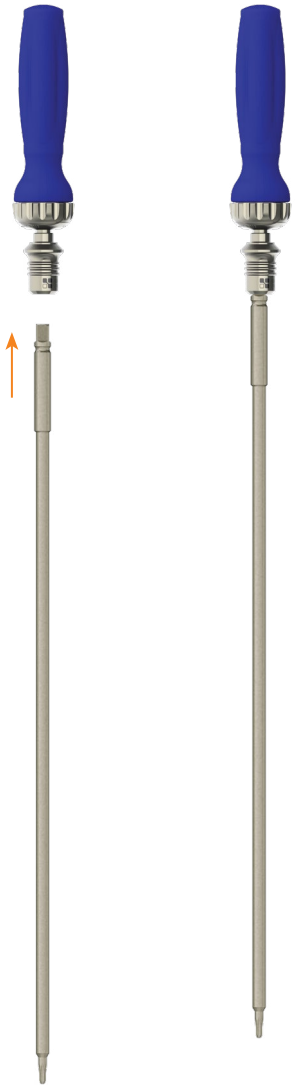


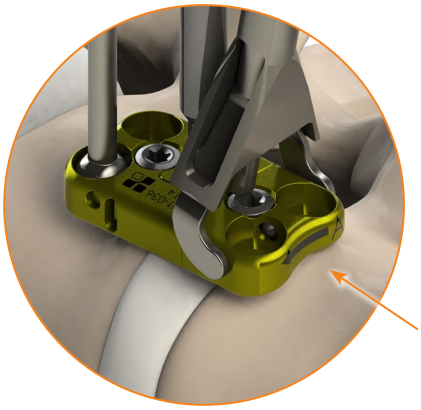
Plate Holder (Optional)

Plate Gear Driver

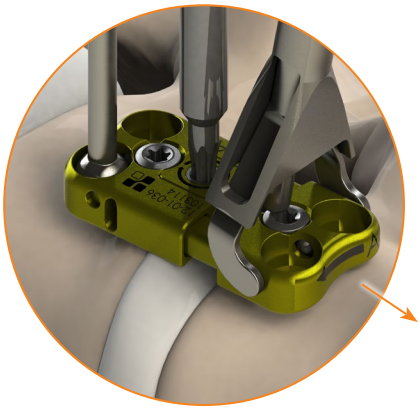


Once the Temporary Long Fixation Pin is in place, the plate length may be adjusted with the Plate Gear Driver.

Attach the preferred handle and insert driver into plate gear adjuster screw.



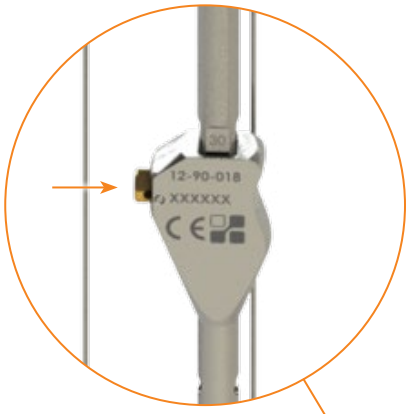
Push down and turn handle counter-clockwise to contract plate length



Push down and turn handle clockwise to expand plate length

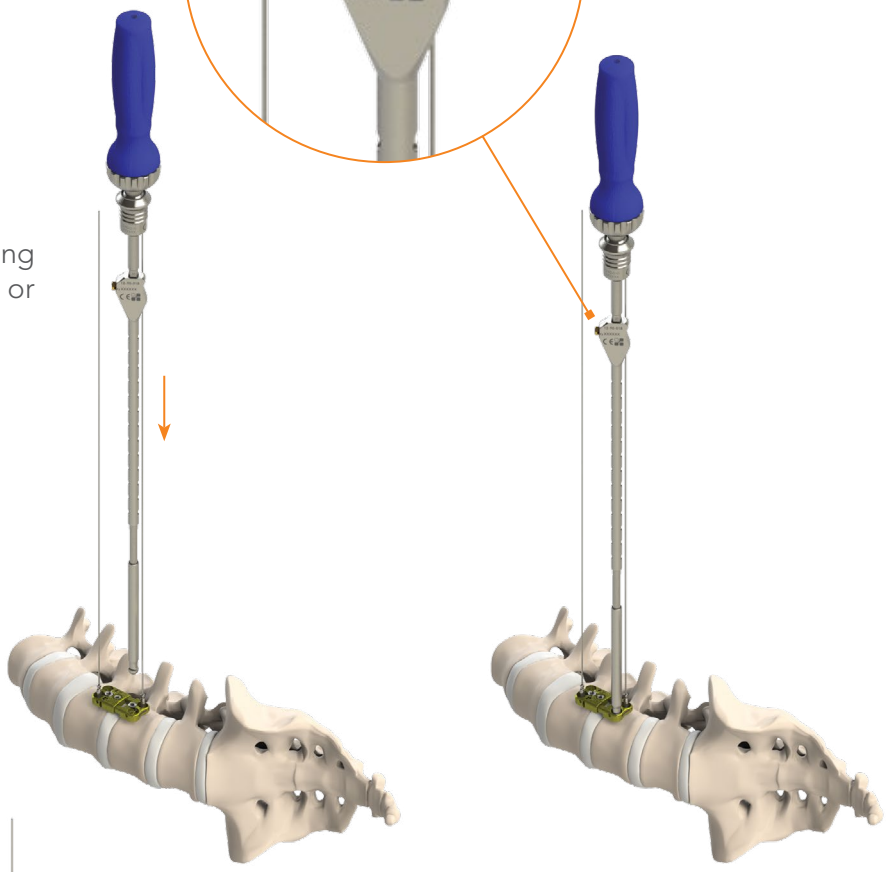
5 Screw Hole Preparation

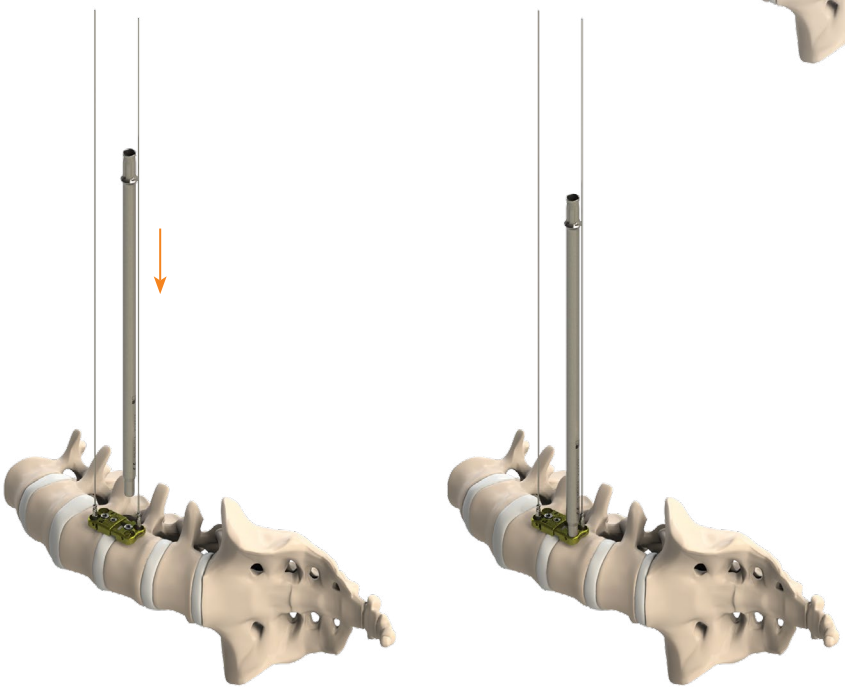
Note: Applicable to all approaches



Adjustable Self-Centering Awl *(Optional)*

Adjust the Self Centering Awl by pushing on the button and moving the sleeve up or down to the desired depth.



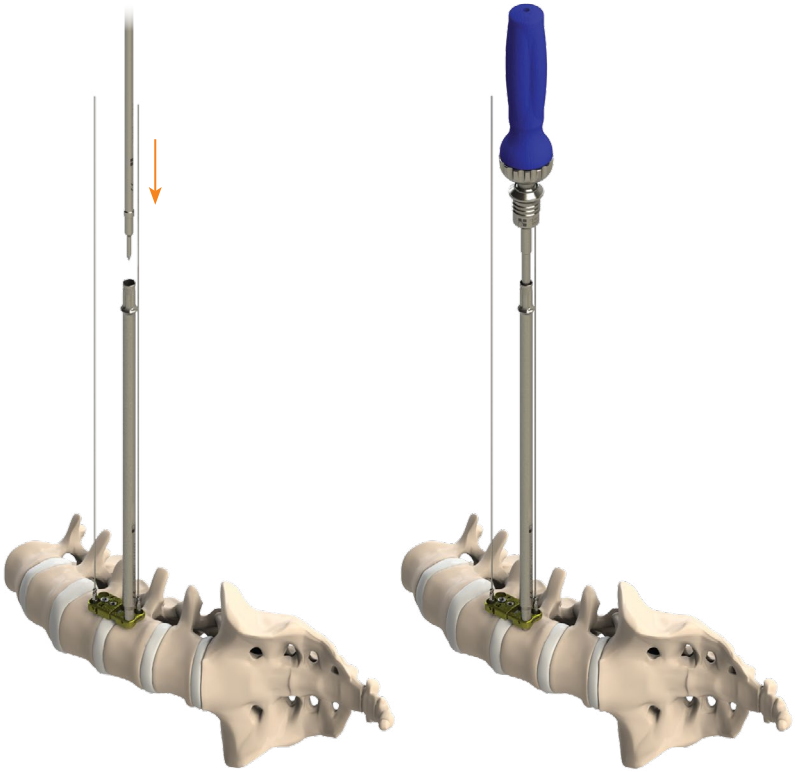


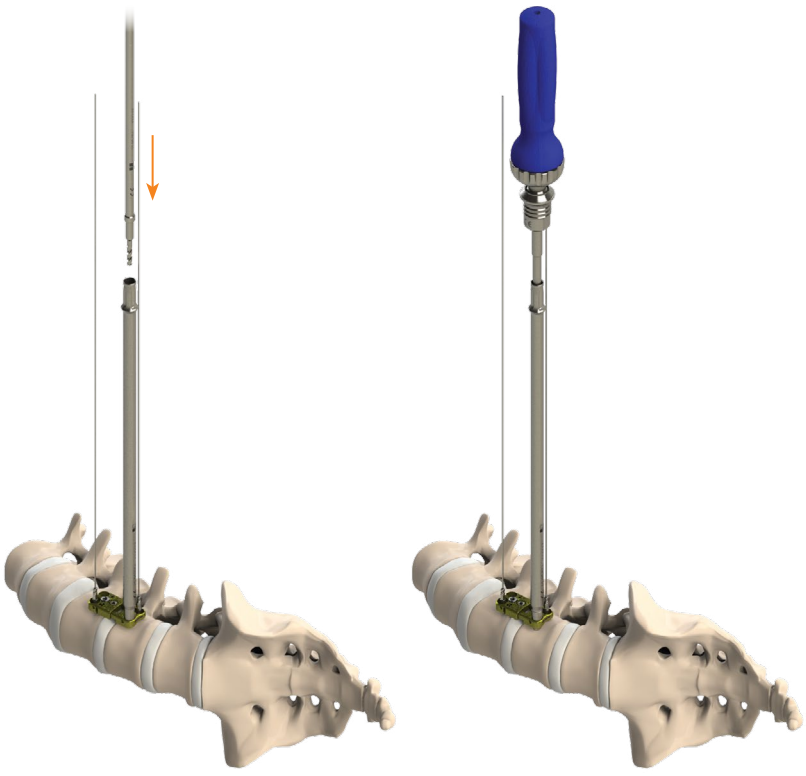
Guide Tube *(Optional)*

When using the Awl, Drill, Tap, Adjustable Awl, Adjustable Drill, and Adjustable Tap; Use the Guide Tube.

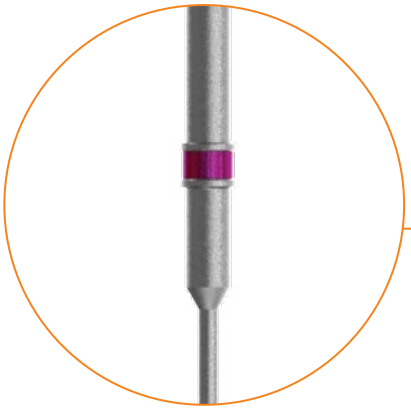
For the Adjustable Awl, Adjustable Drill and Adjustable Tap; Adjust the tool to the desired depth prior to inserting into the Guide Tube.

Awl *(Optional)*





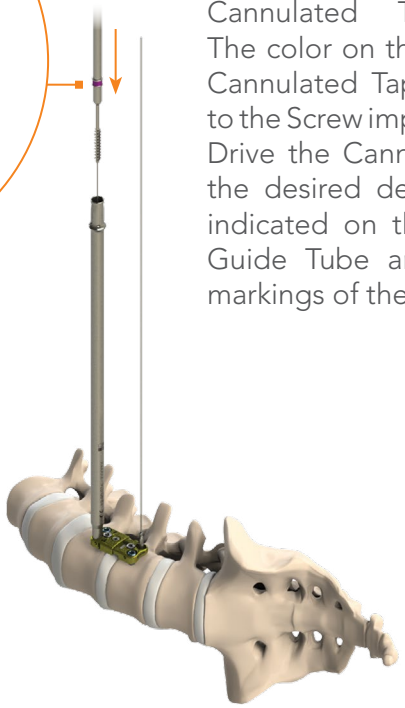
Drill/Adjustable Drill *(Optional)*

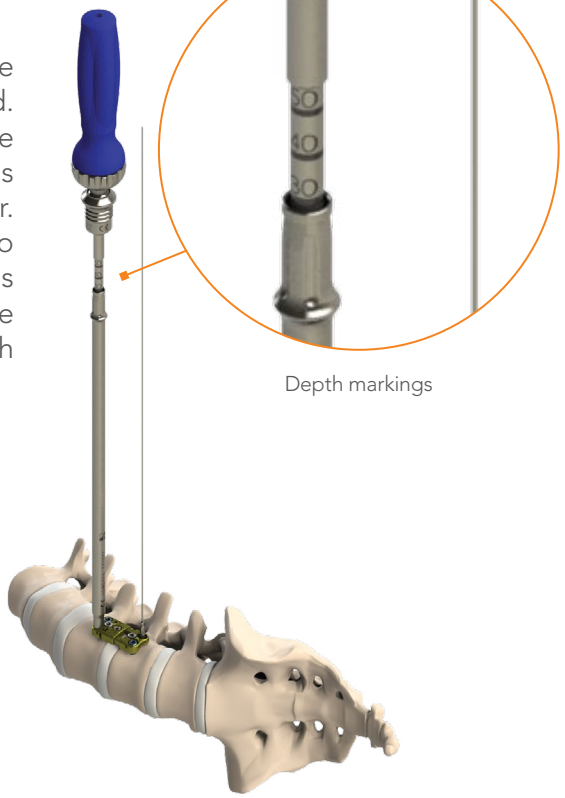


Color band on Cannulated Tap

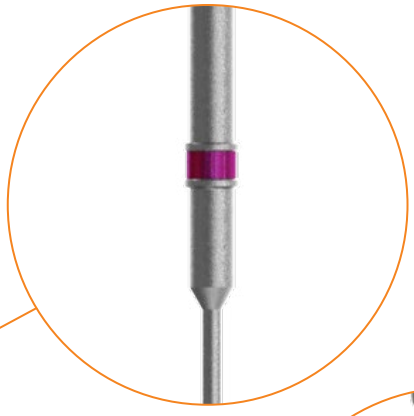
Cannulated Tap

Select the diameter of the Cannulated Tap needed. The color on the band of the Cannulated Tap corresponds to the Screw implant diameter. Drive the Cannulated Tap to the desired depth. Depth is indicated on the top of the Guide Tube and the depth markings of the Tap.

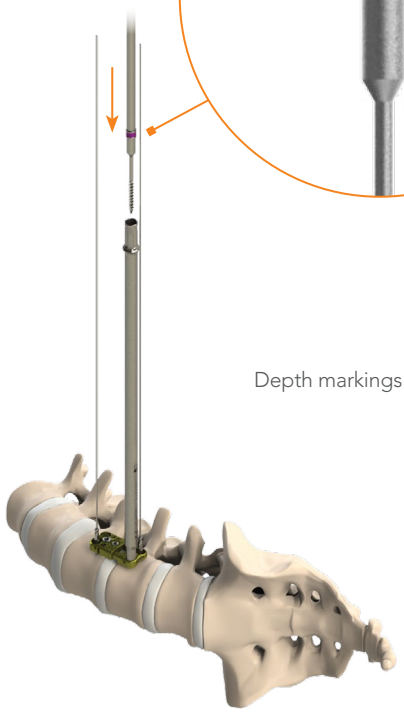




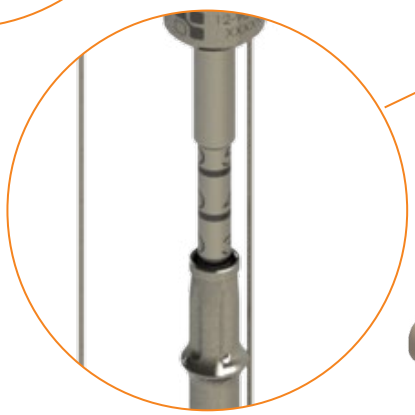
Depth markings

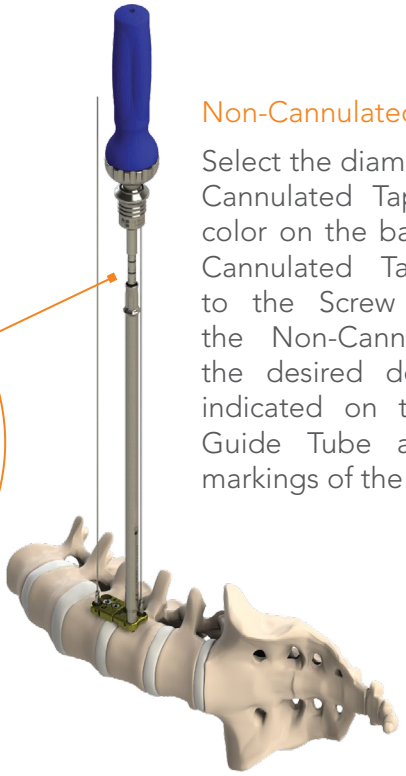


Color band on Non-Cannulated Tap



Depth markings



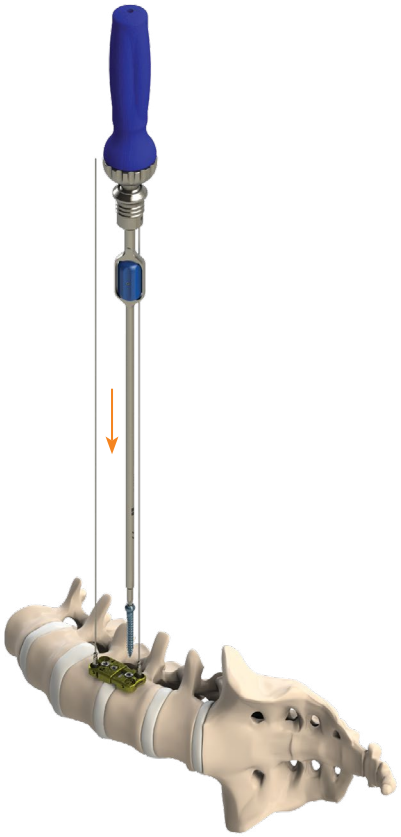


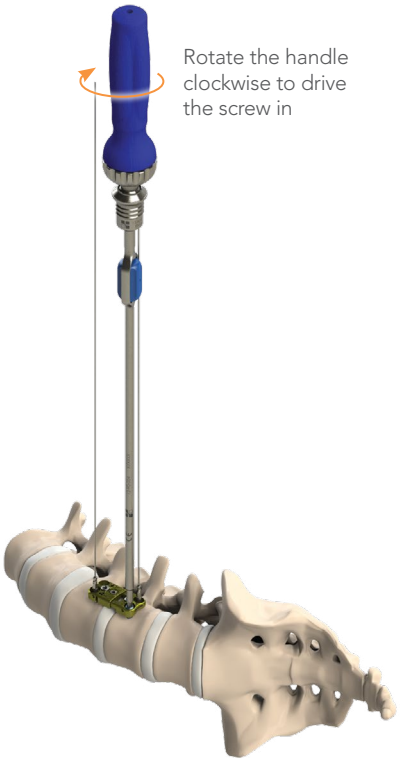
Non-Cannulated Tap *(Optional)*

Select the diameter of the Non-Cannulated Tap needed. The color on the band of the Non-Cannulated Tap corresponds to the Screw implant. Drive the Non-Cannulated Tap to the desired depth. Depth is indicated on the top of the Guide Tube and the depth markings of the Tap.

6 Screw Delivery

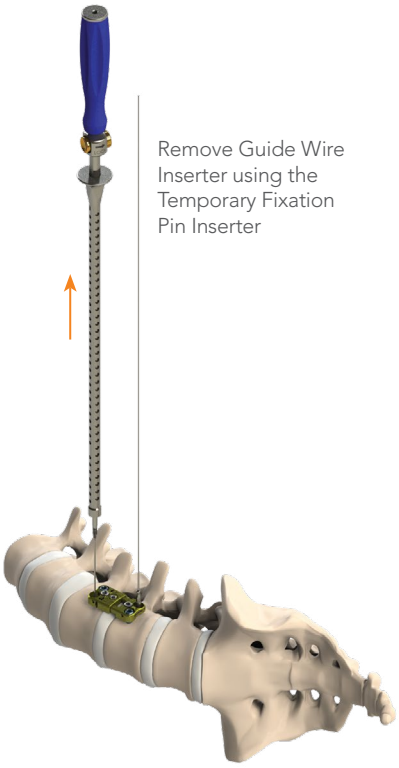
The appropriate length and diameter screw is loaded onto the tip of the Screw Driver. With the screw properly engaged, lock the screw to the driver by rotating the knob clockwise.



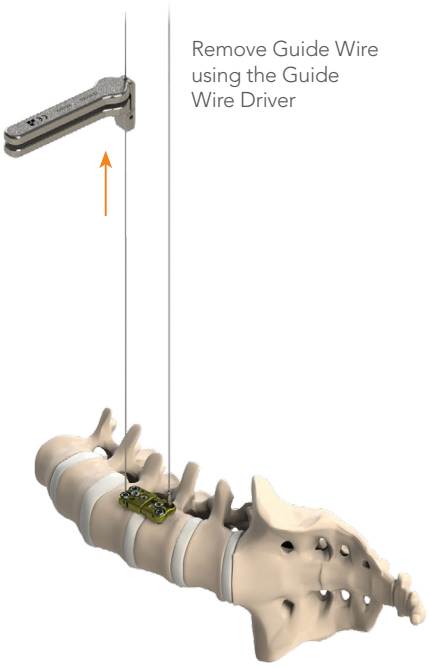


The screw is advanced through the screw hole, using fluoroscopy for depth guidance. With the screw head placed into the plate, detach the Screw Driver and remove it from the screw by rotating the knob counterclockwise. Pilot hole preparation and screw insertion are repeated for the remaining screws.

Note: Applicable to all approaches



Remove Guide Wire Inserter using the Temporary Fixation Pin Inserter



Remove Guide Wire using the Guide Wire Driver

Rotate the handle clockwise to drive the screw in

Note: When using the guide wire: Insert cannulated screw using the Cannulated Screw Driver.

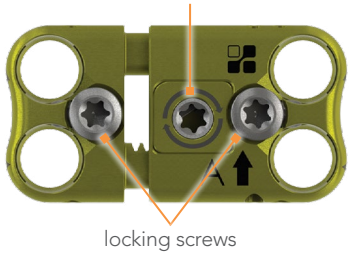
Remove Guide Wire Inserter using the Temporary Fixation Pin Inserter

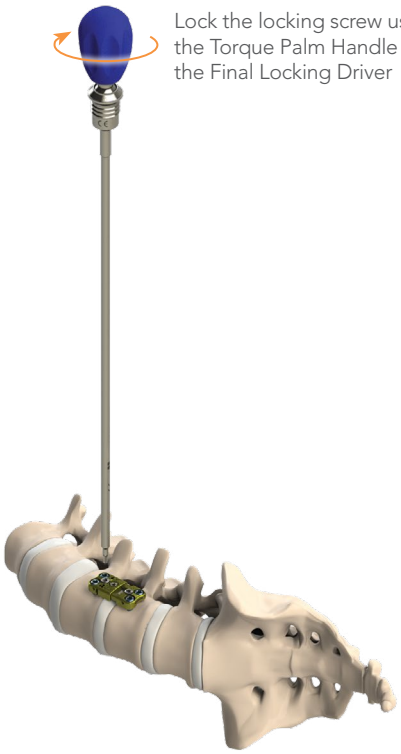
Note: It is important to verify the screws are properly seated under fluoroscopy before final tightening to ensure lock engagement and integrity.

7 Implant Locking

Perform final tightening by rotating the Torque Palm Handle clockwise until an audible click is heard. Repeat final tightening using this technique for the remaining locking screws.

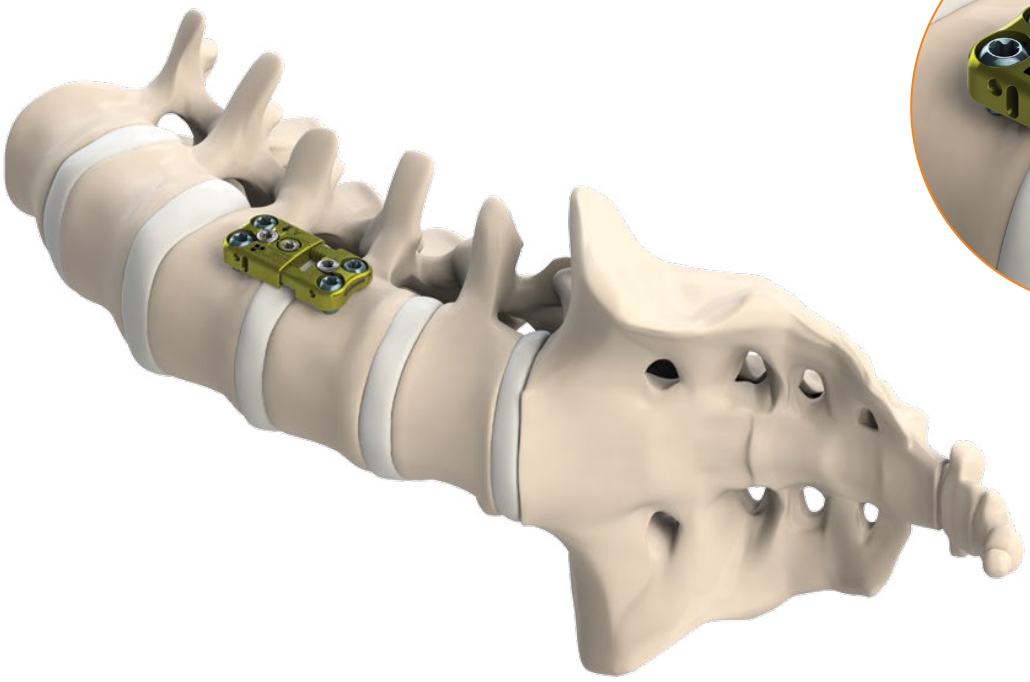
Note: Applicable to all approaches

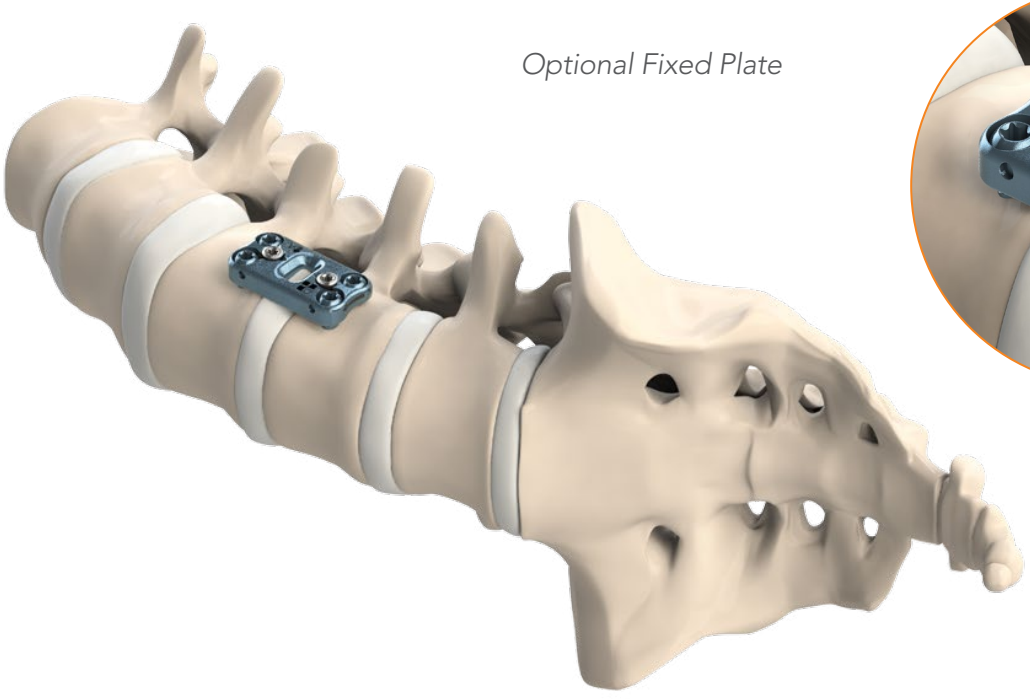




Note: For final tightening, use only the Torque Palm Handle to prevent over-tightening.

8 Final Position

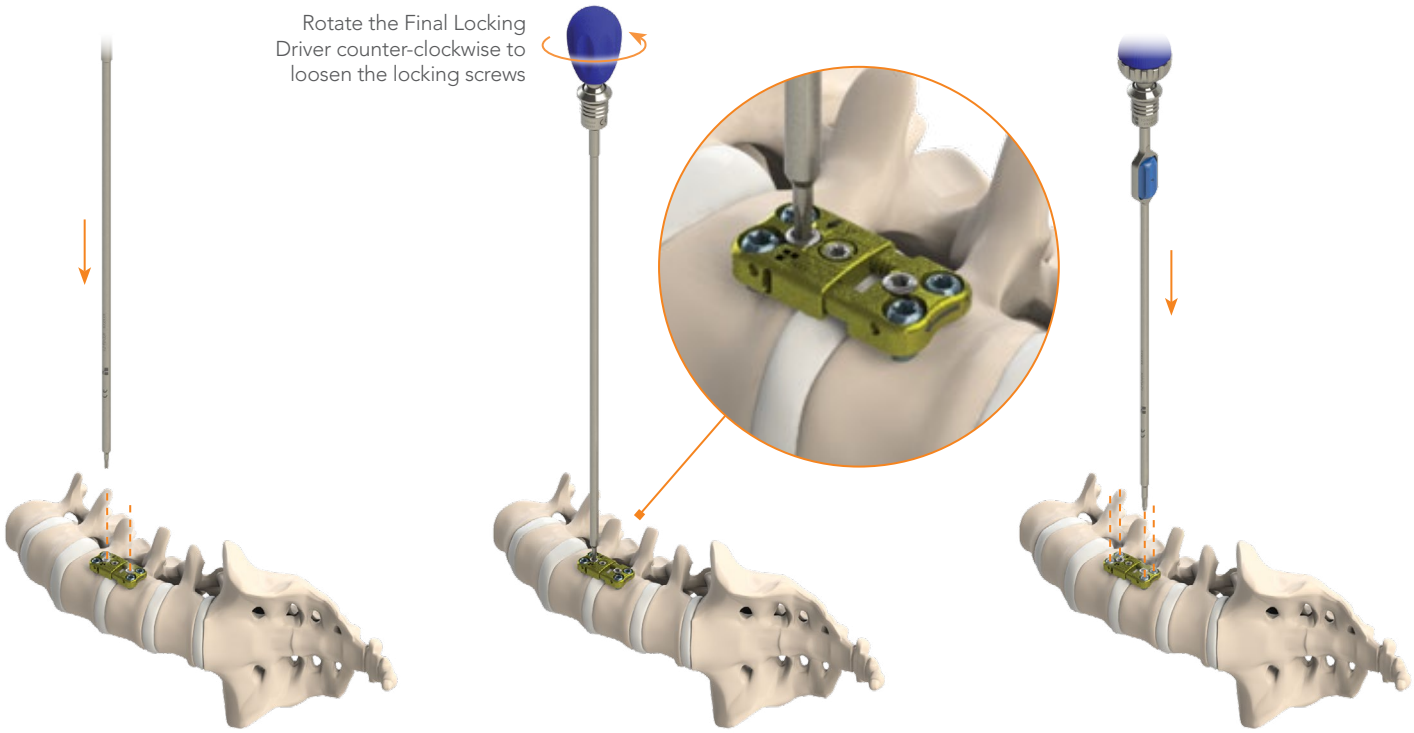


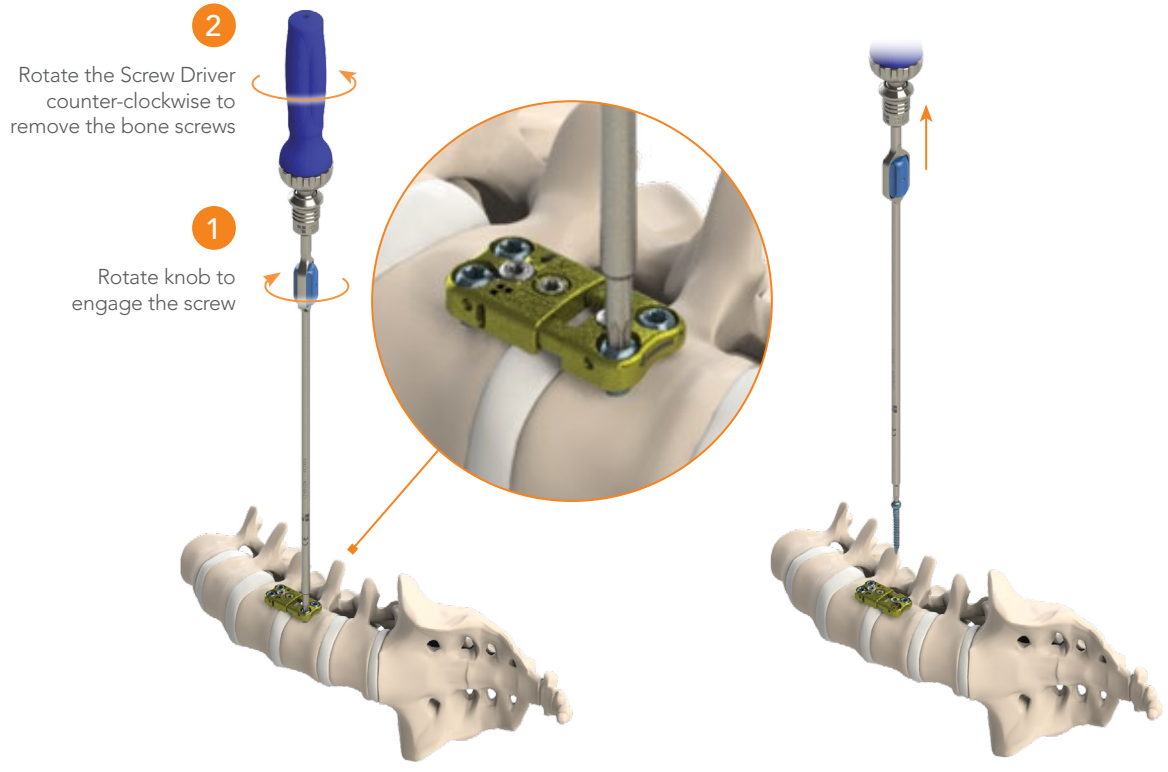


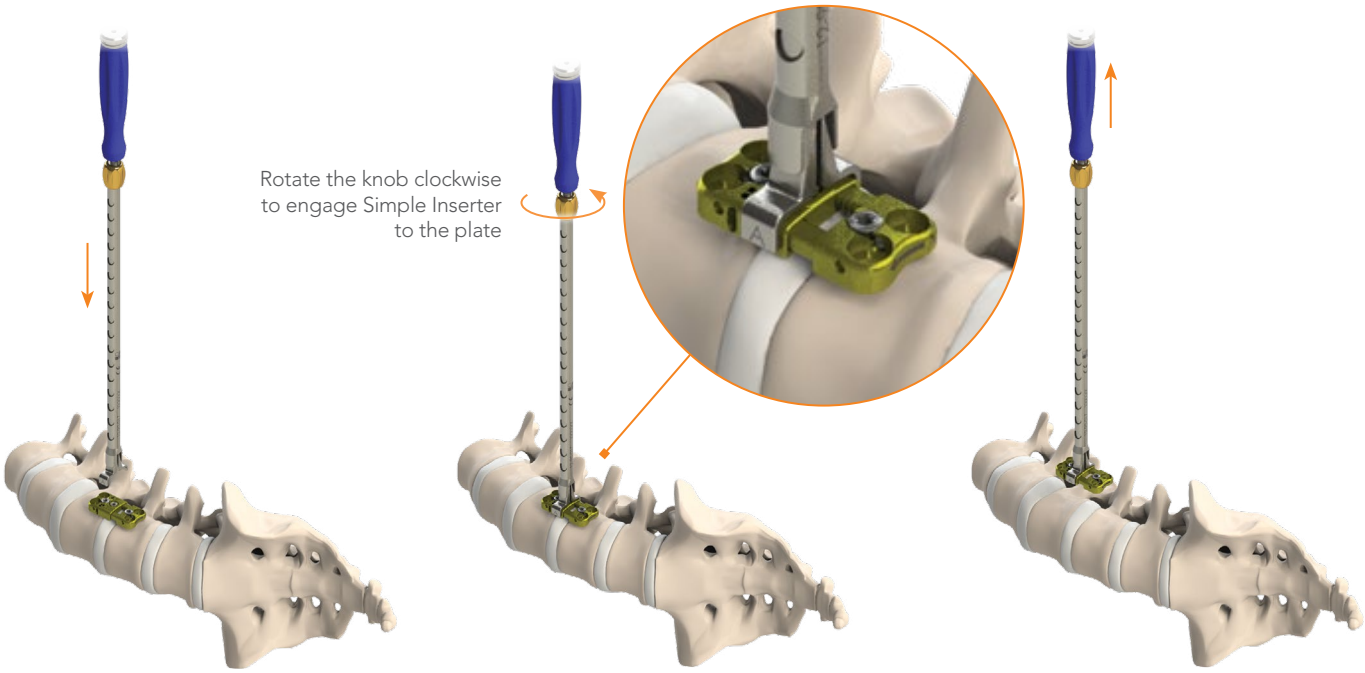
Optional Fixed Plate

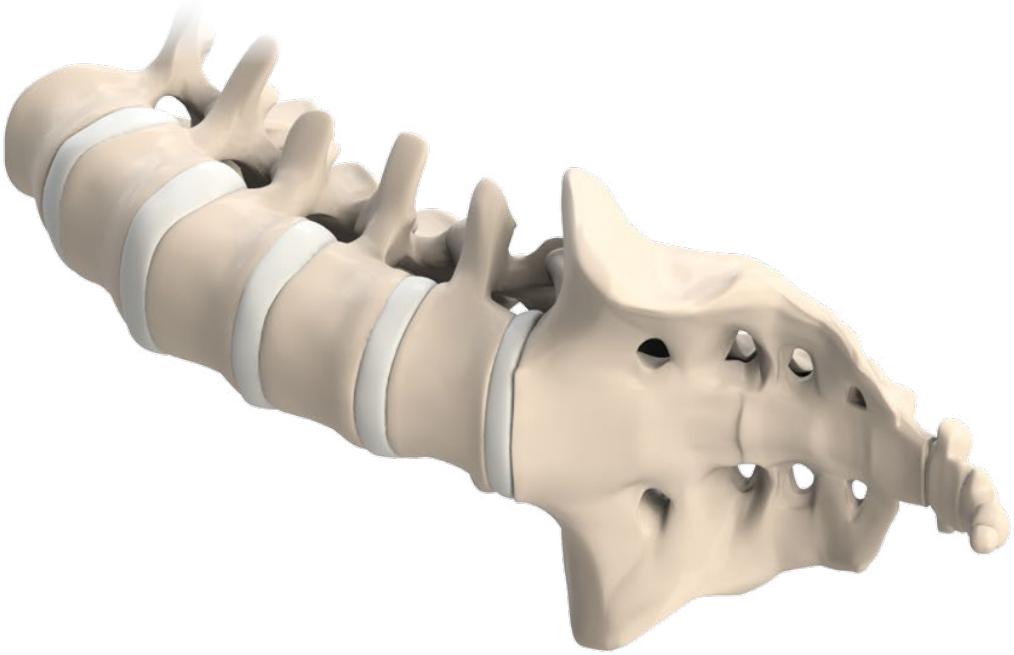
9 Implant Removal

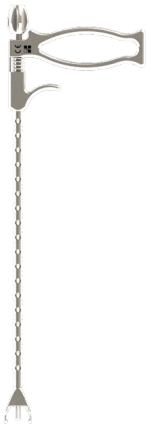
Loosen the two final locking screws with the Final Locking Driver (care should be given not to completely remove the locking screws from the plate). Remove the four bone screws with the Screw Driver. Grab plate with the Simple Inserter or Plate Holder and remove from operative site.






Rotate the knob clockwise
to engage Simple Inserter
to the plate





12-90-001
Plate Holder

12-90-002
Plate Holder with
Drill Guide

12-90-003
Plate Gear Driver

12-90-004
Screw Driver

12-90-005
Awl

12-90-006
Drill

12-90-007-XX
Non-Cannulated Tap

12-90-009
Final Locking Driver

12-90-010
Axial Ratcheting Handle

12-90-011
Non-Ratcheting
Palm Handle

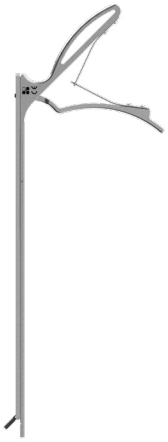
12-90-012
Ratcheting T-Handle

12-90-014
Temporary Fixation
Pin Inserter

12-90-016
Drill, Awl, and Tap
Guide Tube

12-90-017
Simple Inserter

12-90-018
Adjustable
Self-Centering Awl



12-90-019
Osteophyte Removal Tool

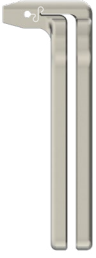
12-90-020
Guide Wire

12-90-021
Guide Wire Inserter

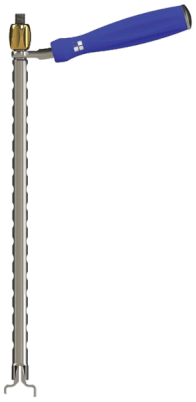
12-90-022
Torque Palm Handle

12-90-023-XX
Cannulated Tap

12-90-024
Cannulated Screw Driver



12-90-025
Guide Wire Driver



12-90-031
Simple Inserter –
Side Handle

12-90-032
Temporary Fixation
Pin Screw Driver

12-90-033
Adjustable Drill

12-90-034
Adjustable Awl

12-90-035
Adjustable
Non-Cannulated Tap

12-90-036
Screw Height Adjuster

Purpose:

The Belvedere Lateral Plating System implant components are temporary implants that are intended for lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (Tl - L5) spine instability.

Description:

The Belvedere Lateral Plating System consists of a variety of bone plates and screws. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the thoracic and thoracolumbar (Tl - L5) spine. Associated instruments are available to facilitate the implantation of the device.

The Belvedere Lateral Plating System implant components are made from titanium alloy such as described by ASTM F136. This material is not compatible with other metal alloys. Do not use any of the Belvedere Lateral Plating System components with the components from any other system or manufacturer. NeuroStructures, Inc. expressly warrants that these devices are fabricated from the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Indications, Contraindications and Possible Adverse Effects

Indications:

The Belvedere Lateral Plating System is indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (Tl - L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of disco genic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

Warning:

This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Contraindications:

Contraindications include, but are not limited to:

- Infection, local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- 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.
- 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.
- Suspected or documented metal allergy or intolerance.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- Any case requiring the mixing of metals from different components.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any case not described in the Indications.
- Any patient unwilling to cooperate with the post-operative instructions.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.

Potential Adverse Events:

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
- 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.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.

- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- 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.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Loss of bowel and/or bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- 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.
- Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
- Non-union (or pseud-arthrosis). Delayed union. Mal union.
- Loss of spinal mobility or function. Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
- Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Change in mental status.
- 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 Belvedere Lateral Plating System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the Belvedere Lateral Plating 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, bending, 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 Belvedere Lateral Plating 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.

Magnetic Resonance Environments:

The Belvedere Lateral Plating System has not been evaluated for safety and compatibility in the MR environment. The Belvedere Lateral Plating 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:

FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN. FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

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. Metallic 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 metal fatigue and consequent

breakage, bending 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:

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- 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.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
- 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 Belvedere Lateral Plating System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative:

- Any available instruction manuals should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at the same location.
- The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
- Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
- Before closing the soft tissues, all of the screws should be seated onto the plate. Recheck the tightness of all screws after finishing to make sure that none has loosened during the tightening of the other screws. Lock the anti-migration caps over the heads of the bone screws. Failure to do so may result in screw loosening. Caution: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

Postoperative:

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

- 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 bending, 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 bending, loosening, 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.
- 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.
- 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.
- If a non-union develops or if the components loosen, bend, 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 bending, 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 insure cooperation until bony union is confirmed.

- The Belvedere Lateral Plating System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. In most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur:
  (1) Corrosion, with localized tissue reaction or pain;
  (2) Migration of implant position possibly resulting in injury;
  (3) Risk of additional injury from postoperative trauma;
  (4) Bending, loosening and or breakage, which could make removal impractical or difficult;
  (5) Pain, discomfort, or abnormal sensations due to the presence of the device;
  (6) Possible increased risk of infection; and
  (7) Bone loss due to stress shielding.

  While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. 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.
- 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 Belvedere Lateral Plating System components should ever be reused under any circumstances.

Packaging:

Packages for each of the components should be intact upon receipt. 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 NeuroStructures, Inc.

Decontamination and Cleaning:

Unless just removed from an unopened package, all instruments and implants must be disassembled, if applicable, and thoroughly cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to NeuroStructures. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

PRE-CLEAN PROCEDURE – INSTRUMENTS ONLY

- It is recommended that instruments should be reprocessed as soon as is reasonably practical following use.
- Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments.
- Open instruments with ratchets, box locks or hinges.
- Remove sharp instruments for manual cleaning or place into a separate tray.
- Lumens/cannula of instruments should be manually processed prior to cleaning. Lumens/cannula should first be cleared of debris. Lumens/cannula should be brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brushes should be tight-fitting. Brush size should be approximately the same diameter of the lumen/cannulation to be cleaned. Using a brush that is too big or too small for the diameter of the lumen/cannulation may not effectively clean the surface of a lumen/cannulation. After brushing lumens/cannula, blow clean compressed air through lumen/cannulation to clear debris, if necessary.
- Soak and/or rinse heavily soiled instruments or cannulated instruments prior to cleaning to loosen any dried soil or debris. Use a neutral pH enzymatic soak or detergent to soak devices. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration. Use cold tap water to rinse instruments.
- Do not use saline or chlorinated solutions.
- Belvedere Lateral Plating System instruments must be cleaned separately from Belvedere Lateral Plating System instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable.

MANUAL CLEANING PROCEDURE – INSTRUMENTS ONLY

Equipment: various sized soft-bristled brushes, lint-free cloths, syringes, pipettes, and/or water jet, neutral enzymatic cleaner or neutral detergent with a pH between 7 and 9.

- Rinse soiled instrument under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to assist in the removal of gross soil and debris.
- Soak instrument in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.

- Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.
- Manually clean instrument for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other movable instrument features to expose all areas to the detergent solution, if applicable. Clean instrument under water to prevent aerosolization of contaminants. Note: fresh solution is a newly- made, clean solution.
- Rinse instrument thoroughly with deionized (DI) or purified (PURW) water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable instrument features in order to rinse thoroughly under running water, if applicable.
- Visually inspect instrument. Repeat the manual cleaning procedure (steps 2- 6) until no visible soil remains on instrument.
- Perform a final rinse on instrument using DI or PURW water.
- Dry device using a clean, soft, lint-free cloth, or clean compressed air.

Cycle	Minimum Time (Minutes)	Minimum Temperature/Water	Type of Detergent
Rinse 1	2	Cold tap water	N/A
Soak	10	Cold to warm tap water	Neutral enzymatic pH between 7 – 9
Rinse 2	2	Cold tap water	N/A
Wash	5	Warm tap water (>40°C)	Detergent with pH between 7 – 9
Rinse 3	2	Warm DI or PURW (>40°C)	N/A
Final Rinse	2	Cold DI or PURW	N/A

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning. No visual contamination shall be present after cleaning, so the instruments shall be re-cleaned if they are not visually clean.

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

It is recommended that devices should be reprocessed as soon as is reasonably practical following use.

Visually inspect all reusable devices for signs of wear and tear before each use. Any devices with corrosion, discoloration, or cracked seals should be returned to the manufacturer.

Sterilization:

Unless noted otherwise on the package labeling, the Belvedere Lateral Plating System components are provided non-sterile. These products need to be steam sterilized by the hospital using one of the following methods:

Steam Sterilization Cycle Type	Exposure time at 132 °C (270 °F)	Drying Times
Dynamic Air Removal: Pre-Vacuum	4 min	20 – 30 min

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. After surgery, immediately decontaminate, clean, and resterilize before handling or (if applicable) return to NeuroStructures, Inc.

Implants and instruments are provided non-sterile.

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, NeuroStructures, Inc. Further, if any of the implanted Belvedere Lateral Plating 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 NeuroStructures, Inc. 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 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 manufacturer 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:

NeuroStructures, Inc., 199 Technology, Suite 110, Irvine, CA 92618, 800-352-6103

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Irvine, CA 92618
Ph/Fax: 800.352.6103

neurostructures.com

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