

## Surgical Technique

### **Valiant™ Anterior Lumbar Plate**

A low profile solution for anterior surgery

- SphereLock™ screw locking technology designed to prevent screw backout and maximizes load sharing
- Tapered plate design allows for easier plate placement in tight spaces



**BIOMET**<sup>®</sup>  
SPINE

## Contents

Introduction .....	Page 1	Instructions for Use .....	Page 13
Indications .....	Page 1	Contraindications .....	Page 14
Implant Features .....	Page 2	Warnings .....	Page 14
Instruments .....	Page 4	Precautions .....	Page 15
Surgical Technique .....	Page 6	Potential Adverse Effects and Complications .....	Page 16
Implant Removal .....	Page 11	Sterilization .....	Page 16
Indications for Use .....	Page 11	Further Information .....	Page 17
Product Information .....	Page 12		
Description of Device .....	Page 13		

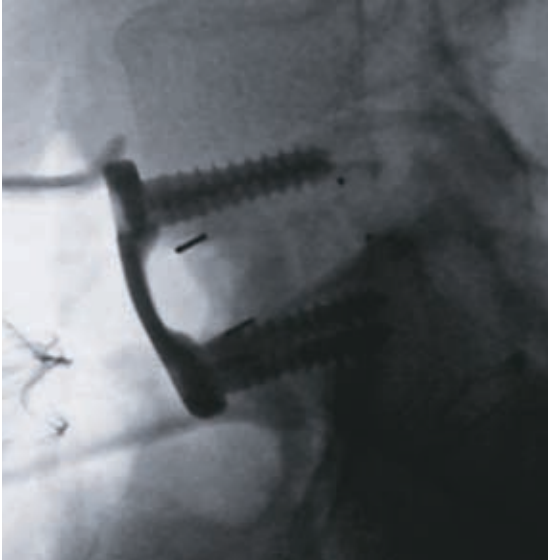


## *Introduction*

The Valiant™ Anterior Lumbar Plate System is a complete set of implants and instruments designed for anterior stabilization of the lumbar spine. The Valiant™ Anterior Lumbar Plate System is low profile and tapered to fit the natural contours of the lower lumbar anatomy.

The system features:

- Novel SphereLock™ locking technology making screw placement simple and secure
- Sacral plates for direct anterior placement below the bifurcation of the great vessels
- Lumbar plates for anterior or anterolateral placement depending on the location of the bifurcation of the great vessels



## *Indications*

The Valiant™ Anterior Lumbar Plate System is an anterior or anterolateral spinal fixation device indicated for use via lateral or anterolateral surgical approach above the bifurcation of the great vessels or anterior approach, below the bifurcation of the great vessels in the fusion of the lumbar or lumbosacral spine at levels L1 through S1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of solid spinal fusions in patients with degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma including fractures, tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis, spondylosis, spondylolisthesis, stenosis and/or failed previous fusion.



## Implant Features

### Plate Specifications:

- SphereLock™ locking technology is designed to prevent screw backout
- Low profile (2.5mm)
- Two pre-bent lordotic options
  - Lumbar: 100mm
  - Lumbosacral: 50mm
- Smooth edges and contoured angles guard against damage to surrounding anatomy
- Available in lengths 33mm–45mm (2.0mm increments)
- Made of titanium alloy (Ti-6Al-4V ELI)
- Tapered design allows insertion in tight spaces

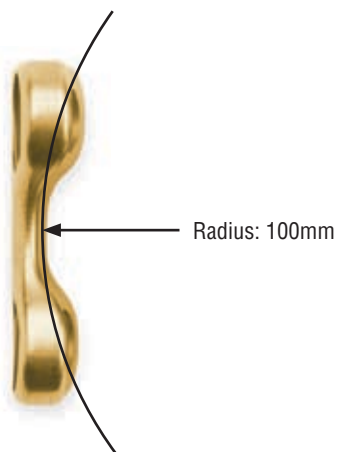


Lengths Measured From Plate Top Edge to Bottom Edge

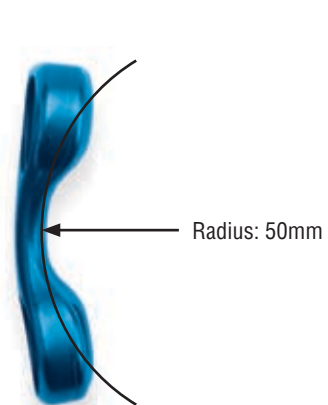
10° Convergent Screw Angle



Lumbar Plate

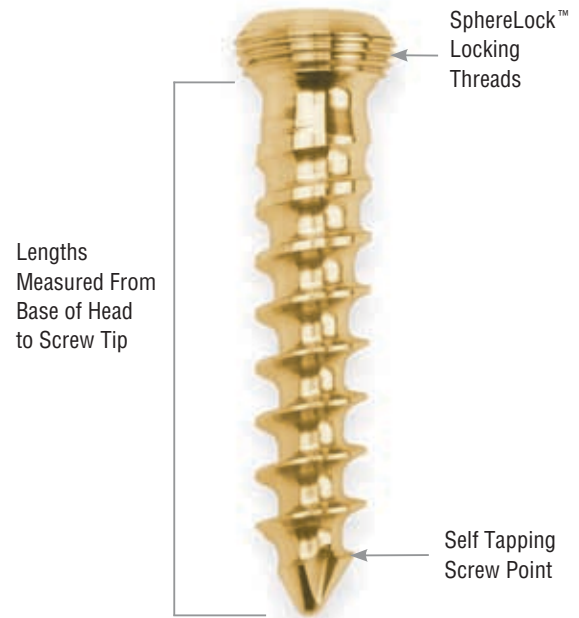


Lumbosacral Plate



**Screw Specifications:**

- Diameters
  - 5.5mm
  - 6.25mm
- Available in 20mm–34mm lengths (2.0mm increments)
- Coarse thread pitch for cancellous bone purchase
- Self-tapping to ease insertion
- Blunt tip screw point
- Pentalobe self-retaining screw driver interface



5.5mm Diameter Screw



6.25mm Diameter Screw



## Instruments



### Centering Post (14-530240)

Inserts into plate holes to help align threaded drill guides.



### Threaded Drill Guide

Threads onto plate. Ensures proper trajectory of Awls, Drills and Screws. Available in Short 2" (14-530250) and Standard 12" (14-530215) lengths.



### Short Guide Inserter/Remover (14-530251)

Quick "couples" or connects to Short 2" drill guide (14-530250) to aid guide insertion and removal.



### Temporary Tack (14-530249)

Used through the Threaded Drill Guide to provisionally secure the plate to the bone.

- Used along with **Temporary Tack Inserter (14-530248)**



### Screw Remover (14-530219)



**Mallet (14-530935)**

Also functions as a slap hammer.



**Awl (14-530216)**

Used with the Threaded Drill Guides to break through the cortex of the vertebral body.



**Drill (14-530217)**

Used with the Threaded Drill Guides.



**Pentalobe Screwdriver Shaft, self retaining (14-530218)**

Used with Ratcheting Handle (14-530239) for screw insertion. Also used with Torque Limiting Handle (14-530220), for final tightening.



**Straight Ratchet Handle (14-530226)**



**Torque Limiting Handle (14-530220)**

70 in. lbs.

## Surgical Technique

### Step 1

After surgical exposure and implantation of autograft, allograft or cleared interbody device, remove any visible osteophytes so the plate can lie flush on the vertebral bodies.

### Step 2 – Plate Size Selection

Select the appropriate plate size so that it bridges the intervertebral space and the screw holes lie close to both inferior and superior vertebral endplates.

**NOTE:** The blue 50mm curved pre-bent lumbosacral plates are designed for use at L5-S. The gold 100mm curved pre-bent lumbar plates are designed for L1-L5.

**WARNING:** Bending the plate is not recommended. The plate holes can deform, compromising the screw locking mechanism, and screw trajectory.

### Step 3 – Plate Attachment

#### Option 1 – Standard Drill Guide

While the desired length plate is in the plate sterilization caddy, insert the centering post (14-530240) into one of the plate's screw holes. Once the centering post is positioned, the standard drill guide (14-530215) is then slid over the centering post and threaded into the plate. After the standard drill guide is secured to the plate, remove the centering post. Repeat steps for remaining three standard drill guides. Once attached the drill guides may be used as a plate holder for positioning on the spine.



Step 3



Option 1





---

**Option 2 – Short Drill Guide**

While the desired length plate is in the plate sterilization caddy, insert the centering post (14-530240) into one of the plate's screw holes. Once the centering post is positioned, the short drill guide (14-530250) is then slid over the centering post and threaded into the plate. After the short drill guide is secured to the plate, remove the centering post. Attach the remaining three short or standard drill guides in a similar manner. The short guide inserter/remover (14-530251) can then be attached to one of the short drill guides and used as a plate holder for positioning on the spine.



Step 3 – Option 2

## ***Surgical Technique (Continued)***

### **Step 4 – Plate Positioning**

Position the plate so that the screws can be implanted close to the vertebral endplates.



### **Step 5 – Provisional Plate Fixation**

Provisionally fix the plate onto the bone by inserting the Temporary Tacks (14-530249) through the Drill Guides. It is recommended that Tacks are placed in contralateral screw holes. Light impaction with a Mallet (14-530935) may be necessary.



### Step 6 – Hole Preparation

While plate is in position insert the Awl (14-530216) through the Drill Guide to perforate the cortical bone. The maximum awl penetration through the drill guide is 20mm. Fluoroscopy can be taken at this point to determine the appropriate screw length.

If necessary the Drill (14-530217) can also be used to further prepare the cortical bone for screw insertion. The maximum penetration for both of used instruments through the drill guide is 20mm.



### Step 7 – Screw Selection

Select the appropriate length 5.5mm diameter screw. Screw lengths range from 20mm–34mm in 2.0mm increments. 6.25mm diameter screws are also available as a rescue screw.

**NOTE:** Screws are color coded by length.



## *Surgical Technique (Continued)*

### **Step 8 – Insert Screws**

Use the Self-Retaining Pentalobe Screw Driver (14-530218) to insert the screw through the drill guide and thread into a prepared hole.

Remove any Temporary Tack(s) and repeat steps for remaining screw hole(s).



### **Step 9 – Final Tightening/Seating**

Attach the Torque Limiting Handle (70 in. lbs) (14-530220) to Pentalobe Screw Driver (14-530218). An audible click will be heard when the screw has reached proper torque.

**NOTE:** Final seating with the torque limiting T-handle is only done after all screws have been inserted, and threaded to the plate.



## ***Implant Removal***

The plate and screws can be removed with the same instrumentation that was used to implant them. Reattach the drill guide to the plate. Use the straight handle with the screw driver shaft and place down the drill guide to engage the screw. The driver may then be turned in a counterclockwise fashion until the screw is disengaged and removed. Repeat this process on all four screw holes then remove the plate.

If necessary, the screw remover shaft may be used in the pentalobe recess of the screw. Attach the screw remover shaft to the straight handle and rotate counter-clockwise into the compromised pentalobe recess of the screw. The screw remover shaft will retain the screw as the screw is unthreaded from the plate.



Screw Remover (14-530225)

## ***Indications for Use***

The Valiant™ Anterior Lumbar Plate System is an anterior or anterolateral spinal fixation device indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels in the fusion of the lumbar or lumbosacral spine at levels L1 through S1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of solid spinal fusions in patients with degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma including fractures, tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis, spondyloysis, spondylolisthesis, stenosis and/or failed previous fusion.

## Product Information

### Implant

Catalog #	Description
14-530150	Lumbar Plate, 33mm (Gold)
14-530151	Lumbar Plate, 35mm (Gold)
14-530152	Lumbar Plate, 37mm (Gold)
14-530153	Lumbar Plate, 39mm (Gold)
14-530154	Lumbar Plate, 41mm (Gold)
14-530155	Lumbar Plate, 43mm (Gold)
14-530156	Lumbar Plate, 45mm (Gold)
14-530160	Lumbosacral Plate, 33mm (Blue)
14-530161	Lumbosacral Plate, 35mm (Blue)
14-530162	Lumbosacral Plate, 37mm (Blue)
14-530163	Lumbosacral Plate, 39mm (Blue)
14-530164	Lumbosacral Plate, 41mm (Blue)
14-530165	Lumbosacral Plate, 43mm (Blue)
14-530166	Lumbosacral Plate, 45mm (Blue)
14-530190	5.5mm x 20mm Pentalobe Screw
14-530191	5.5mm x 22mm Pentalobe Screw
14-530192	5.5mm x 24mm Pentalobe Screw
14-530193	5.5mm x 26mm Pentalobe Screw
14-530194	5.5mm x 28mm Pentalobe Screw
14-530195	5.5mm x 30mm Pentalobe Screw
14-530196	5.5mm x 32mm Pentalobe Screw
14-530197	5.5mm x 34mm Pentalobe Screw
14-530200	6.25mm x 20mm Pentalobe Screw
14-530201	6.25mm x 22mm Pentalobe Screw
14-530202	6.25mm x 24mm Pentalobe Screw
14-530203	6.25mm x 26mm Pentalobe Screw
14-530204	6.25mm x 28mm Pentalobe Screw
14-530205	6.25mm x 30mm Pentalobe Screw
14-530206	6.25mm x 32mm Pentalobe Screw
14-530207	6.25mm x 34mm Pentalobe Screw

### Instrument

Catalog #	Description
14-530215	Drill Guide - Standard
14-530216	Awl - Standard
14-530217	Drill - Standard
14-530218	Pentalobe Screw Driver - Standard
14-530219	Screw Remover - Standard
14-530220	Torque Handle
14-530226	Ratcheting Straight Handle
14-530240	Centering Post
14-530225	Screw Remover
14-530248	Tack Inserter
14-530249	Plate Tacks
14-530250	Short Guide (2")
14-530251	Short Guide Inserter/Remover
14-530935	Slotted Mallet

### Loaner Kit

Catalog #	Description
14-530227	Instrument Loaner Kit
14-530228	Implant Loaner Kit

## *Description of Device*

The Valiant™ Anterior Lumbar Plate System is a supplemental fixation system consisting of a variety of shapes and size of plates and screws. The Valiant™ Anterior Lumbar Plate is available in curvatures of 50mm and 100mm with lengths from 33mm to 45mm. The screws feature a locking head and are available in diameters of 5.5mm and 6.25mm in lengths of 20mm to 34mm. The Valiant™ Anterior Lumbar Plate System is made from titanium alloy (Ti-6Al-4V ELI) described by ASTM Standard F136.

## *Instructions for Use*

**CAUTION:** The Valiant™ Anterior Lumbar Plate System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgical techniques.

## *Contraindications*

Contraindications include, but are not limited to,

1. Infection, systemic, spinal or localized;
2. Morbid obesity;
3. Signs of local inflammation;
4. Fever or leukocytosis;
5. Metal sensitivity/allergies to the implant materials;
6. 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;
7. Grossly distorted anatomy due to congenital abnormalities;
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. Any case not needing a bone graft and fusion or where fracture healing is not required;
10. Any case requiring the mixing of metals from different components;
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 case not described in the indications;
13. Any patient unwilling to cooperate with the postoperative instructions;
14. Any time implant utilization would interfere with anatomical structures or expected physiological performance.

## *Warnings*

The surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants.
2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
3. All instruments must be cleaned and sterilized prior to surgery.
4. As with all orthopaedic implants, the Valiant™ Anterior Lumbar Plate System should never be reused under any circumstances.
5. Proper implant selection and patient compliance to post-operative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
6. Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.



## **Precautions**

---

### **Preoperative**

Only patients that meet the criteria described in the indications should be selected. Patient conditions and/or pre-dispositions such as those addressed in the Contraindications Section 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. All instruments should be cleaned and sterilized before use.

### **Intraoperative**

Any instruction manuals should be carefully followed. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in a loss of neurological functions. Bone grafts may be placed in the area to be fused.

### **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 an 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 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, 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. If a nonunion 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 nonunion 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 radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the Valiant™ Anterior Lumbar Plate System components should ever be reused under any circumstances.

## ***Potential Adverse Effects and Complications***

Possible adverse effects include, but are not limited to,

1. Bending, loosening or fracture of the implants or instruments;
2. Loss of fixation;
3. Sensitivity to a metallic foreign body, including possible tumor formation;
4. Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications;
5. Nonunion or delayed union;
6. Infection;
7. Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage;
8. Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
9. Pain or discomfort;
10. Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery (fracture of the vertebra);
11. Hemorrhage of blood vessels and/or hematomas;
12. Malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height;
13. Bursitis;
14. Bone graft donor site pain;
15. Inability to resume activities of normal daily living;
16. Reoperation or
17. Death.

## ***Sterilization***

The Valiant™ Anterior Lumbar Plate System is provided nonsterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended.

Cycle: High Vacuum

Temperature: 270°F/132°C

Time: 8 minutes

**NOTE:** Allow for cooling. Individuals not using the recommended method, temperature and time are advised to validate any alternative methods or cycles using an approved method of standard.

**CAUTION:** Federal (USA) law restricts these devices to sale by or on the order of a licensed physician.

## ***Further Information***

This brochure describes the surgical technique used by Charles Banta, MD, Frank Kuwamura, MD, Vikas Patel, MD, and John Gorup, MD. The surgeon who performs any implant procedure is responsible for determining the appropriate products(s) and utilizing the appropriate technique(s) for said implantation in each individual patient. The contents of this manual are intended to be only a guide and are not intended to set a standard of care.

For further information, please contact the Customer Service Department at:

Biomet Spine  
100 Interpace Parkway  
Parsippany, NJ 07054  
973.299.9300 • 800.526.2579  
[www.biometspine.com](http://www.biometspine.com)









At Biomet, engineering excellence is our heritage and our passion. For over 25 years, through various divisions worldwide, we have applied the most advanced engineering and manufacturing technology to the development of highly durable systems for a wide variety of surgical applications.

### **Valiant™ Anterior Lumbar Plate**

A low profile solution for anterior surgery

To learn more about this product,  
contact your local Biomet Sales Representative today.



100 Interpace Parkway • Parsippany, NJ 07054  
800.526.2579 • [www.biometspine.com](http://www.biometspine.com) • BSP216555L 10/10  
©2010 EBI, LLC. All trademarks are the property of Biomet, Inc.  
or one of its subsidiaries unless otherwise indicated. Rx Only.